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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act and Public Health Service Act to advance the next-generation of clinical development of novel treatments and cures, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. AUCHINCLOSS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and Public Health Service Act to advance the next-generation of clinical development of novel treatments and cures, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Faster Clinical Trials Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—EMBEDDING CLINICAL STUDIES IN ROUTINE HEALTH CARE

Sec. 101. Cures in Care Initiative.
Sec. 102. Cures in Care Initiative lead network grant program.
Sec. 103. Cures in Care Initiative Collaborative.
Sec. 104. Definitions for Cures in Care Initiative and related activities.
Sec. 105. Data standards with respect to data sharing.
Sec. 106. Clinical trial oversight modernization.
Sec. 107. Updates to patient costs and payment for participation in clinical trials.

TITLE II—MODERNIZED PRECLINICAL AND EARLY-STAGE CLINICAL DEVELOPMENT

Sec. 201. Modernized evidence generation through new approach methodologies.
Sec. 202. Modernized phase 1 clinical trial oversight.
Sec. 203. Global regulatory alignment to modernize clinical development.
Sec. 204. Minimum United States representation in clinical trials.
Sec. 205. Food and Drug Administration Rare Disease Innovation Hub.

TITLE III—ENHANCED FOOD AND DRUG ADMINISTRATION REGULATIONS TO SUPPORT INNOVATION

Sec. 301. Resolving clinical holds and improving clinical trial efficiency.
Sec. 302. Mutual recognition of GMP standards.
Sec. 303. Pathway for competitive generic therapies.
Sec. 304. Biosimilar biological products.
Sec. 305. Certification of patent information in certain applications for biological products.
Sec. 306. GAO report.
Sec. 307. Definitions.

TITLE IV—PRECISION ONCOLOGY MODERNIZATION

Sec. 401. Findings and purpose.
Sec. 402. Oncology center of excellence.
Sec. 403. Labeling revisions for genomic exclusions in oncology drugs.

TITLE V—AMERICAN FRONTIER BIOBANK

Sec. 501. Establishment of the American Frontier Biobank.

TITLE I—EMBEDDING CLINICAL STUDIES IN ROUTINE HEALTH CARE

SEC. 101. CURES IN CARE INITIATIVE.

(a) IN GENERAL.—Part J of title IV of the Public Health Service Act (42 U.S.C. 290c et seq.) is amended by adding at the end the following:

"SEC. 499B. CURES IN CARE INITIATIVE ESTABLISHMENT.

''(a) CENTER FOR CLINICAL TRIAL INNOVATION.—The Secretary shall establish the Center for Clinical Trial Innovation (in this section referred to as the 'Center') within the Center for Drug Evaluation and Research of the Food and Drug Administration to carry out the Initiative established under subsection (b), to be headed by a director.

''(b) ESTABLISHMENT OF CURES IN CARE INITIATIVE.—

''(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary of Health shall continue a Cures in Care Initiative (in this section referred to as the 'Initiative') to expand, enhance, and promote routine point-of-care clinical trials, including through the establishment and support of broad-based clinical trial networks (in this section referred to as a 'lead network'), for the purpose of accel-

erating the development of new treatments and cures by generating clinical evidence faster and through novel methods.

''(2) COORDINATION AND IMPLEMENTATION.—The Assistant Secretary of Health shall coordinate the activities of the Commissioner of Food and Drugs and the Director of the National Institutes of Health in implementing the Initiative.

''(3) PRINCIPAL OFFICE.—The Secretary shall establish the Center for Clinical Trial Innovation (in this section referred to as the 'Center') within the Center for Drug Evaluation and Research of the Food and Drug Administration to serve as the principal implementing office supporting the Assistant Secretary of Health in carrying out the Initiative established under subsection (a), to be headed by a director.

''(c) DUTIES.—In carrying out the Initiative, the Director shall—

''(1) identify priority disease or mechanism areas for the purpose of implementing lead networks;

''(2) establish lead networks for each such a priority disease or mechanism area by building on existing clinical trial networks and infrastructures;

''(3) ensure each such network prioritizes the participation of less-resourced clinical trial settings;

''(4) ensure each such network focuses on not less than—

''(A) 1 high-burden chronic disease; and

''(B) 1 group of rare diseases that are related or similar to each other;

''(5) designate a central institutional review board to review any routine point-of-care clinical trial carried out by a lead network pursuant to this subsection;

''(6) coordinate actions carried out under the Initiative for purposes of addressing barriers to the conduct of routine point-of-care clinical trials carried out by a lead network pursuant to this subsection, with respect to—

''(A) shared or central institutional review board oversight;

''(B) patient consent, including electronic consent;

''(C) alignment of health information technology interoperability standards adopted by the Office of the National Coordinator for Health Information Technology, program data requirements administered by the Centers for

Medicare and Medicaid Services and the real-world data standards maintained by the Commissioner of Food and Drugs, consistent with applicable privacy and confidentiality protections;

''(D) development of innovative clinical trial methods;

''(E) publication transparency and reproducibility;

''(F) digital tools and artificial intelligence to reduce the cost and burden of such clinical trials;

''(G) necessary infrastructure to implement a decentralized clinical trial network, in a hub-and-spoke model; and

''(H) governance of such clinical trials at multiple sites;

''(7) establish an Food and Drug Administration-endorsed clinical trial site certification program; and

''(8) in consultation with the Director of the National Center for Advancing Translational Sciences award grants and enter into contracts, cooperative agreements, and other transactions, including as authorized under sections 499A(g) and 499C.

''(d) RAPID IMPLEMENTATION.—The Director shall—

''(1) establish not less than 3 lead networks under subsection (c) not later than 1 year after the date of enactment of this subsection; and

''(2) upon establishment of such lead networks, develop the plan described in subsection (e).

''(e) IMPLEMENTATION PLAN FOR EXPANDING ACTIVITIES.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of this subsection, the Director shall implement a comprehensive implementation plan describing how the Initiative will broadly extend covered activities to the public and private development of medical products, including stretch goals with timeframes for—

''(A) achieving expanded patient access and site access to routine point-of-care clinical trials, including ensuring patient access at 60 percent of health care delivery sites and for 90 percent of eligible patients that participate in a clinical trial carried out by a lead network established under subsection (c);

''(B) reducing the cost of such a clinical trial, including approaching a 30 to 50 percent

reduction in cost per patient and a 30 percent reduction in accrual time;

''(C) enhancing any impact of such a clinical trial, including ensuring that 90 percent of patients participating in such a clinical trial obtain a timely, independently-reviewed, and publicly-reported result; and

''(D) assessing if lead networks are improving trial execution, including site activation timelines, time to first patient enrolled, enrollment and retention performance, data quality, monitoring burden, technology and workflow readiness, and the long-term research readiness of participating sites.

''(2) PUBLICATION.—Not later than 3 years after the date of enactment of this paragraph, the Director shall make available to the public on the website of the Department of Health and Human Services the implementation plan implemented under paragraph (1).

''(3) COVERED ACTIVITY DEFINED.—For purposes of paragraph (1), the term 'covered activity' means—

''(A) identifying priority disease or mechanism areas under subsection (c) for the purpose

of implementing broad-based point-of-care clinical trial networks; or

''(B) establishing a lead network under such subsection for each such priority disease or mechanism area.

''(f) COLLABORATION AND CONSULTATION.—

''(1) REQUIRED COLLABORATION AND CONSULTATION.—In carrying out the Initiative, the Director shall collaborate and consult with—

''(A) the Administrator of the Centers for Medicare & Medicaid Services;

''(B) the Director of the Advanced Research Projects Agency–Health;

''(C) the Administrator of the Health Resources and Services Administration;

''(D) the Office of the National Coordinator for Health Information Technology;

''(E) the Director of the Center for Biologics Evaluation and Research;

''(F) the Office of the Assistant Secretary of Health; and

''(G) representatives from—

''(i) health care organizations in a lead network;

''(ii) network users, including researchers and clinical trial administrators;

''(iii) provider groups that do not directly collaborate with lead networks, including health systems, academic medical centers, and specialty medical societies;

''(iv) private and nonprofit organizations funding such organizations and groups;

''(v) patient advocacy organizations;

''(vi) contract research organizations;

''(vii) technology partners; and

''(viii) such other partner organizations as the Director determines appropriate.

''(2) ADDITIONAL COLLABORATION AND CONSULTATION.—In addition to the collaboration and consultation required under paragraph (1), the Director may, as appropriate, collaborate and consult with—

''(A) the Secretary of Veterans Affairs; and

''(B) the Secretary of Defense, including the Director of the Defense Health Agency.

''(g) TRAINING AND TECHNICAL ASSISTANCE.—

''(1) IN GENERAL.—In carrying out the Initiative, the Director, in consultation with the Director of the National Center for Advancing Translational Sciences, shall provide training and technical assistance to—

''(A) a lead network established under subsection (c);

''(B) a health care organization or other partner organization seeking to participate in a routine point-of-care clinical trial carried out by a lead network;

''(C) any entity that applies for a grant, cooperative agreement, contract, or other transaction under section 499C but does not receive such grant, cooperative agreement, contract, or other transaction; and

''(D) an emerging biotechnology company.

''(2) CONTENTS.—In providing training and technical assistance under paragraph (1), the Director may address clinical development and regulatory subjects, including—

''(A) protocol development;

''(B) regulatory interactions with the Food and Drug Administration;

''(C) data infrastructure integration;

''(D) sponsor and site engagement in designing, conducting, and evaluating clinical trials;

''(E) sustainability planning; and

''(F) general public education on clinical trials and their potential risks and benefits.

''(3) FORMAT.—The Director shall make these training and technical assistance materials available in an online resource center, including resources on—

''(A) staff training materials;

''(B) trial-network participation;

''(C) technology support;

''(D) data quality assessments;

''(E) Institutional Review Board templates and best practices;

''(F) study startup; and

''(G) capacity building.

''(4) PRIORITY.—In carrying out this subsection, the Director shall give priority to less-resourced clinical trial settings.

''(5) CONTRACTS AND COOPERATIVE AGREEMENTS FOR TRAINING.—The Director may enter into contracts or cooperative agreements with entities, such as the Reagan-Udall Foundation for the

Food and Drug Administration established under section 770 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd), to—

''(A) establish training programs; and

''(B) hold meetings for health care organizations, clinical research organizations, technology partners, and patient-led organizations participating in a lead network established under subsection (c).

''(h) EXTERNAL ENGAGEMENT.—The Commissioner of Food and Drugs shall establish and expand the external engagement capacity of the Center through the performance commitments under section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2).

''(i) FDA GUIDANCE.—Not later than 18 months after the date of enactment of this subsection, the Commissioner of Food and Drugs shall, in consultation with the Director, issue any draft or final guidance as may be necessary to carry out this section, including with respect to—

''(1) guidelines for carrying out routine point-of-care clinical trial networks, including governance, data monitoring, and application of an innovative clinical trial method, drawing on existing Food and Drug Administration guidance for platform studies;

''(2) any update to guidance on decentralized clinical trials, remote monitoring of such trials, and real-world data and real-world evidence; and

''(3) reliance on central institutional review boards and electronic consent in routine point-of-care clinical trials.

''(j) REPORTS.—

''(1) ANNUAL REPORTS.—Not later than 1 year after the date of enactment of this paragraph, and annually thereafter, the Director shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and make available to the public on the website of the Department, a report on, with respect to the period covered by the report, the progress of the Initiative in advancing routine point-of-care clinical trials, with respect to each priority disease or mechanism area and lead network established under subsection (c), including—

''(A) progress addressing any barrier described in such subsection;

''(B) the availability and performance of any routine point-of-care clinical trial in the United States;

''(C) any trend in the United States with respect to such clinical trials; and

''(D) the participation rate of less-resourced clinical trial settings in each such lead network.

''(2) EVALUATION REPORTS.—

''(A) 3-YEAR REPORT.—Not later than 3 years after the date of enactment of this subparagraph, the Director shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

''(i) an evaluation of—

''(I) the outcome of any coordination, collaboration, and consultation required under this section, including the performance of each lead network established under subsection (c);

''(II) any expanded patient access and site access to routine point-of-care clinical trials that is attributable to the Initiative;

''(III) any improvement in the participation rate of less-resourced

clinical trial settings that is attributable to the Initiative;

''(IV) any improvement in the participation rate of emerging biotechnology sponsors within the lead network; and

''(V) alignment of interagency action under this section; and

''(ii) any recommendation for additional legislative action to accelerate progress in carrying out routine point-of-care clinical trials and developing medical products.

''(B) 5-YEAR REPORT.—Not later than 5 years after the date of enactment of this subparagraph, the Director shall submit a report in such manner and containing such information as required under subparagraph (A).

''(k) MEDICAL PRODUCT DEFINED.—In this section, the term 'medical product' means—

''(1) a drug or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

''(2) a biological product, as defined in section 351 of this Act.

''(l) AUTHORIZATION OF APPROPRIATIONS.—In addition to any funds made available in the FDA Innovation Account under section 1002(b)(2)(A) of the 21st Century Cures Act (Public Law 114–255) and any amount made available under section 499C, there is authorized to be appropriated to carry out this section $500,000,000 for each of fiscal years 2027 through 2031, to remain available until expended.''.

(b) FDA INNOVATION ACCOUNT.—

(1) TRANSFER OF DIRECT SPENDING SAVINGS.—Section 1002(b)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended to read as follows:

''(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

''(i) For fiscal year 2027, $20,000,000.

''(ii) For fiscal year 2028, $60,000,000.

''(iii) For fiscal year 2029, $70,000,000.

''(iv) For fiscal year 2030, $75,000,000.

"(v) For fiscal year 2031, $70,000,000.".

(2) AUTHORIZATION OF APPROPRIATIONS.—Section 1002(b)(3) of the 21st Century Cures Act (Public Law 114–255) is amended by striking "2017 through 2025" each place such term appears and inserting "2027 through 2031".

(3) FDA ACTIVITIES.—Section 1002(b)(4) of the 21st Century Cures Act (Public Law 114–255) is amended to read as follows:

"(4) FDA ACTIVITIES.—The activities authorized to be funded under this section are the activities under—

"(A) section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357);

"(B) section 1014 of such Act (21 U.S.C. 399g); and

"(C) section 499B of the Public Health Service Act, as added by section 101(a) of the Faster Clinical Trials Act.".

(c) CONFORMING AMENDMENT.—Part J of Title IV of the Public Health Service (42 U.S.C. 290c et seq.) is further amended by striking "**ADVANCED RESEARCH PROJECTS AGENCY–HEALTH**" in the part heading and

inserting ''**ADVANCED HEALTH RESEARCH PROJECTS**''.

SEC. 102. CURES IN CARE INITIATIVE LEAD NETWORK GRANT PROGRAM.

Part J of title IV of the Public Health Service Act (42 U.S.C. 290c et seq.) is amended by adding at the end the following:

''SEC. 499C. CURES IN CARE INITIATIVE LEAD NETWORK GRANT PROGRAM.

''(a) IN GENERAL.—Not later than 5 years after the date of enactment of this subsection, the Commissioner of Food and Drugs, in consultation with the director of the Center for Clinical Trial Innovation, and the Director of the National Institutes of Health, acting through the Center for Advancing Translational Sciences and the Advanced Research Projects Agency–Health, (in this section referred to as the 'Commissioner and Director') shall make grants to, or enter into cooperative agreements, contracts, or other transactions with, not fewer than 3 lead networks established under section 499B(c) to—

''(1) achieve not later than 3 years after the date on which an appropriation is first made under subsection (e), measurable improvements in the clinical evidence base for each priority disease or mecha-

nism area for which such network was established; and

''(2) enable broader implementation of routine point-of-care clinical trials beyond such lead network.

''(b) USE OF FUNDS.—The Commissioner and Director may require a lead network that receives a grant, or enters into a cooperative agreement, contract, or other transaction, under this section to use any funding received through such grant, cooperative agreement, contract, or transaction to—

''(1) implement the data sharing standards described under section 105 of the Faster Clinical Trials Act;

''(2) implement site data infrastructure and clinical research technology;

''(3) leverage existing clinical trial networks, Federal digital health and artificial intelligence initiatives, and virtual participation options, consistent with good clinical practice;

''(4) provide a plan for reliable collection and sharing of data on covariates, treatments, outcomes, and adverse events with respect to the applicable disease or mechanism area;

''(5) support, as appropriate—

''(A) phase 2 and 3 clinical trials;

''(B) label expansion studies;

''(C) comparative effectiveness studies; and

''(D) post-market commitments and phase 4 commitments;

''(6) include sites and patients from less-resourced clinical trial settings;

''(7) include patients from populations not primarily served by academic health centers;

''(8) include emerging biotechnology companies;

''(9) establish grants specifically for less-resourced sites, including federally qualified health centers, to enable participation;

''(10) collaborate or partner with multiple commercial developers of medical products (as defined in section 499B) that are active in the applicable disease or mechanism area; and

''(11) include a plan for sustainability with respect to a routine point-of-care clinical trial carried out by such platform, including a description of—

''(A) any partial startup funding from a non-Federal source;

''(B) an additional study on the common trial platform to be carried out after the date

on which the period described in subsection (c) ends; and

''(C) an understanding of how lead networks will maintain infrastructure and research beyond initial Federal support, including long-term site readiness, staffing and workforce support, technology maintenance, continued community-site participation, sponsor adoption and utilization, and the operational resources necessary to support multiple studies over time.

''(c) DURATION.—

''(1) IN GENERAL.—Subject to paragraph (2), a grant, cooperation agreement, contract, or other transaction under this section shall be for a period of not more than 5 years.

''(2) EXTENSION FOR MATERIAL CONTRIBUTION.—The Commissioner and Director may extend the 5-year period described in paragraph (1) by not more than 3 years if the Commissioner and Director determine that such extension will materially contribute to fulfillment of the implementation plan required under section 499B.

''(d) EVALUATION.—

''(1) IN GENERAL.—The Cures in Care Initiative Collaborative established under section 499D

shall evaluate any activity carried out using any funds received through a grant, cooperative agreement, contract, or transaction under this section, including—

''(A) a partnership between a lead network and a sponsor or health care organization that are additional sites of care;

''(B) compared to traditional baselines, the cost of—

''(i) recruiting, enrolling, and treating each patient enrolled in a routine point-of-care clinical trial; and

''(ii) completing each such trial;

''(C) any research impact such an activity has on—

''(i) such clinical trials;

''(ii) any site in which such a clinical trial is performed; and

''(iii) any effect on the evidence base;

''(D) inclusion of less-resourced clinical trial settings; and

''(E) any opportunity to increase scaling and sustainability with respect to such a clinical trial carried out by a lead network that receives such funds, including—

''(i) maintenance plan for clinical trial sites to continue participating after the initial grant period ends; and

''(ii) continued education for sites and training opportunities for staff.

''(2) PUBLICATION.—Not later than 3 years after the date of enactment of this paragraph, and annually thereafter, the Collaborative shall make available to the public on the website of the Department of Health and Human Services the evaluation carried out under paragraph (1).

''(e) BUDGET CLARIFICATION; AGENCY CONTRIBUTIONS.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as necessary for each of fiscal years 2027 through 2031, to remain available until expended.

''(2) COMMON FUND.—The Commissioner and Director may reserve to carry out this section any amounts made available under paragraph (1) for the Common Fund established under section 402A(c)(1).

''(3) BUDGET CLARIFICATION.—Any budget request of the President shall specify an amount for carrying out this section.

''(4) AGENCY CONTRIBUTIONS.—In addition to any funds made available under section 402A(a)(3), the Secretary may transfer funds from other departmental agencies and programs to carry out the Initiative established under section 499B, including the grant program established under this section, provided such funds do not supplant funding under such section and such transfer will further the authorized programs of the contributing agency or program.''.

SEC. 103. CURES IN CARE INITIATIVE COLLABORATIVE.

Part J of title IV of the Public Health Service Act (42 U.S.C. 290c et seq.) is amended by adding at the end the following:

''SEC. 499D. CURES IN CARE INITIATIVE COLLABORATIVE.

''(a) IN GENERAL.—The Secretary, acting through the Director of NIH and the Director of the Center for Clinical Trial Innovation, shall establish, through entering into a contract, cooperative agreement, memorandum of understanding, or other mechanism, a public-private partnership, to be known as the Cures in Care Initiative Col-

laborative (in this section referred to as the 'Collaborative'), to—

''(1) promote routine point-of-care clinical trials, including the development of novel trial methodologies;

''(2) promote the elimination of barriers to trial initiation and completion; and

''(3) support lead networks under the Cures in Care Initiative established under section 499B.

''(b) REQUIRED ACTIVITIES.—The Collaborative shall—

''(1) establish user groups, workshops, and other forums for sponsors, contract research organizations, health care organizations, technology providers, patient organizations, and Federal agencies to identify and address implementation barriers to routine point-of-care clinical trials;

''(2) provide technical assistance, including on protocol development, regulatory interactions, and data infrastructure, to sponsors of routine point-of-care clinical trials and lead networks that receive a grant, or enter into a cooperative agreement, contract, or other transaction, under section 499C;

''(3) support sandbox testing of innovations in trial design, data infrastructure, consent, and gov-

ernance prior to broader adoption of such innovations;

''(4) evaluate incentives to support and sustain site participation in clinical trial networks;

''(5) maintain public reporting on progress, barriers, and outcomes of routine point-of-care clinical trial innovation;

''(6) coordinate with—

''(A) existing public-private partnerships on routine point-of-care clinical trial innovation;

''(B) existing research infrastructures within the National Institutes of Health and the Advanced Research Projects Agency–Health; and

''(C) the Center for Medicare and Medicaid Innovation established under section 1115A of the Social Security Act (42 U.S.C. 1315a), except that the Collaborative may not direct, or be directed by, such Center;

''(7) carry out the evaluation required under section 499C(d);

''(8) support practical technology and operational enablement of lead networks, including development and testing of integrated technology packages that can provide participating sites with inter-

operable tools, standardized workflows, training, implementation support, monitoring and data quality capabilities, and centralized technical assistance for less resourced sites; and

''(9) assess opportunities to centralize services, including patient recruitment, to reduce the burden of participation for clinical trial sites.

''(c) FEDERAL ADVISORY COMMITTEE ACT APPLICABILITY.—Chapter 10 of title 5, United States Code, shall not apply to the Collaborative.''.

SEC. 104. DEFINITIONS FOR CURES IN CARE INITIATIVE AND RELATED ACTIVITIES.

Part J of title IV of the Public Health Service Act (42 U.S.C. 290c et seq.) is amended by adding at the end the following:

''SEC. 499E. DEFINITIONS FOR CURES IN CARE INITIATIVE AND RELATED ACTIVITIES.

''In this part:

''(1) CLINICAL INVESTIGATION.—The term 'clinical investigation' has the meaning given such term in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation).

''(2) INNOVATIVE CLINICAL TRIAL METHOD.—The term 'innovative clinical trial method' includes adaptive, decentralized, Bayesian, platform, and ex-

ternal-control trial designs, as such terms are described in guidance issued by the Food and Drug Administration, including pursuant to section 3021 of the 21st Century Cures Act (21 U.S.C. 355 note) and section 3606 of the Consolidated Appropriations Act, 2023 (21 U.S.C. 360a–1 note).

''(3) LEAD DISEASE OR MECHANISM AREA.—The term 'lead disease or mechanism area' means a disease, condition, or disease-mechanism area that presents substantial opportunity for scaled, reusable platforms for routine point-of-care clinical trials.

''(4) LEAD NETWORK.—The term 'lead network' means a network of participating health care organizations for a lead disease or mechanism area.

''(5) LESS-RESOURCED CLINICAL TRIAL SETTING.—The term 'less-resourced clinical trial setting' means a health care organization or provider that—

''(A) is located in, or primarily serves, a medically underserved community (as defined in section 799B(6) of this Act); or

''(B) is—

''(i) a Federally qualified health center (as defined in section 1861 of the Social Security Act (42 U.S.C. 1395x));

''(ii) a rural health clinic (as defined in such section);

''(iii) a critical access hospital (as defined in such section);

''(iv) a health center that, during the period in which such center is in a lead network established under section 499B(c) of this Act, receives a grant under section 330;

''(v) a hospital that, during such period, receives a disproportionate share payment under section 1886(d)(5)(F) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F));

''(vi) a facility owned or operated by the Indian Health Service;

''(vii) a facility operated by an Indian Tribe, Tribal organization, or an urban Indian organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603); or

''(viii) a health care provider that, during such period, receives a grant under title XXVI of the Public Health Service

Act (42 U.S.C. 300ff et seq.) (commonly known as the Ryan White HIV/AIDS program).

''(6) ROUTINE POINT-OF-CARE CLINICAL TRIAL.—The term 'routine point-of-care clinical trial' means a clinical investigation of a medical product (as defined in section 499B of this Act) that—

''(A) is integrated into clinical practice, including routine in-person or virtual visits;

''(B) includes health providers as investigators;

''(C) may be conducted in a primary care setting, an outpatient care setting, the home of a patient participating in such investigation, or a similar location; and

''(D) may follow a streamlined protocol and procedures focused on essential data collection generating or incorporating real-world data from an electronic or other health record.''.

SEC. 105. DATA STANDARDS WITH RESPECT TO DATA SHARING.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services, Commis-

sioner of Food and Drugs, and National Coordinator for Health Information Technology (in this section referred to as the ''Administrator'') shall establish a list of data standards for the purpose of facilitating the exchange of patient data for routine point-of-care clinical trials and contribution to Federal datasets using established common data models.

(b) REQUIRED CONTENTS.—In establishing the list under subsection (a), the Administrator shall include—

(1) the United States Core Data for Interoperability;

(2) the Fast Healthcare Interoperability Resources standard maintained by Health Level Seven;

(3) the Clinical Data Acquisition Standards Harmonization maintained by the Clinical Data Interchange Standards Consortium; and

(4) the Study Data Tabulation Model maintained by such Consortium.

(c) UPDATES TO LIST.—Not less than once every 3 years, the Administrator shall update the list of data standards established under subsection (a) to reflect new or successor standards adopted by the National Coordinator for Health Information Technology pursuant to section 3001 of the Public Health Service Act (42 U.S.C. 300jj–11).

(d) TECHNICAL SPECIFICATIONS AND VALIDATION PATHWAYS FOR DATA EXCHANGE.—Not later than 12 months after the date of enactment of this Act, the Administrator shall make available to the public on the website of the Department technical specifications and validation pathways by which data exchanged, in a manner consistent with the data standards included on the list established under subsection (a), may be translated for regulatory submission.

(e) PRIVACY-PRESERVING DATA SHARING.—The Administrator may implement data linkage and tokenization capabilities maintained by the Centers for Medicare & Medicaid Services to support data sharing in routine point-of-care clinical trials in compliance with—

(1) the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191);

(2) section 552a of title 5, United States Code (commonly referred to as the ''Privacy Act of 1974''); and

(3) part 2 of title 42, Code of Federal Regulations (or any successor regulation), relating to confidentiality of substance use disorder patient records.

(f) IMPLEMENTATION PLAN.—Not later than 90 days after the date of enactment of this Act, the Administrator

shall make available to the public on the website of the Department an implementation plan that—

(1) includes milestones for carrying out each activity under subsections (a) through (e);

(2) designates lead officials at the Centers for Medicare & Medicaid Services, Food and Drug Administration, and Office of the National Coordinator for Health Information Technology to carry out such activities;

(3) describes how such activities align with the Cures in Care Initiative established under section 499B of the Public Health Service Act, as added by section 101 of this Act; and

(4) describes how technology will be implemented in daily clinical workflows, such as telehealth, remote monitoring, eCOA/ePRO, wearables and connected devices, eConsent, EDC, eSource, and EHR integration, with appropriate expectations for validation, interoperability, data quality, privacy, cybersecurity and regulatory use.

(g) AMENDMENT TO FDA GUIDANCE.—Not later than 12 months after the list of data standards is established under paragraph (1), the Commissioner of Food and Drugs shall update the guidance entitled ''Real-World Data: Assessing Electronic Health Records and Medical

Claims Data To Support Regulatory Decision-Making for Drug and Biological Products'' (89 Fed. Reg. 60430; issued July 25, 2024) (or successor guidance) to clarify how a person may use data shared in compliance with such standards when submitting an application seeking approval of a medical product, including for—

(1) demonstrating the effectiveness of—

(A) medical products approved under section 506 or 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356; 21 U.S.C. 360e-3);

(B) a previously approved medical product for a new indication of use; and

(C) a drug designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb);

(2) assessing fit-for-purpose validation of digital health technologies and artificial intelligence tools that capture or analyze such data for clinical investigations of medical products; and

(3) assessing how real-world evidence contained in Federal datasets could be leveraged to support regulatory decision-making for medical product approval applications.

SEC. 106. CLINICAL TRIAL OVERSIGHT MODERNIZATION.

(a) SINGLE IRB REQUIREMENT FOR CERTAIN CLINICAL INVESTIGATIONS.—

(1) IN GENERAL.—Subject to paragraph (2), a sponsor of a multi-institutional or cooperative clinical investigations of medical products regulated under parts 45 and 56 of title 21, Code of Federal Regulations (or any successor regulations), shall designate a single institutional review board with respect to the review of such investigation.

(2) EXCEPTION.—If, in an investigational new drug application or investigational device exemption application, the sponsor described in paragraph (1) demonstrates that an alternative manner of review is necessary and the designation of only one institutional review board is not appropriate, such sponsor may, with respect to a clinical investigation—

(A) rely on the review of an institutional review board local to a site for such clinical investigation;

(B) enter into a joint review arrangement with institutional review boards; or

(C) make such other arrangement to avoid a duplication of effort.

(3) RULEMAKING.—Not later than 12 months after the date of enactment of this Act, the Commis-

sioner of Food and Drugs shall issue such rules as may be necessary to implement this subsection, including—

(A) amending parts 50 and 56 of title 21, Code of Federal Regulations (or any successor regulation); and

(B) ensuring implementation of section 3023 of the 21st Century Cures Act (Public Law 114–255).

(4) DEFINITIONS.—In this subsection:

(A) INVESTIGATIONAL DEVICE EXEMPTION APPLICATION.—The term ''investigational device exemption application'' means an application submitted pursuant to part 812 of title 21, Code of Federal Regulations (or any successor regulation) to request an exemption for an investigational device (as defined in section 812.3 of such part).

(B) MULTI-INSTITUTIONAL CLINICAL INVESTIGATION.—The term ''multi-institutional clinical investigation'' means a clinical investigation conducted at not less than two institutions under a single protocol.

(b) IRB TRANSPARENCY IN DECISION-MAKING.—Not later than 1 year after the date of enactment of this Act,

the Secretary of Health and Human Services, acting through the Assistant Secretary of Health, Commissioner of Food and Drugs, and the Director of the National Institutes of Health shall issue such rules as may be necessary to amend title 21 and title 45, Code of Federal Regulations (and any successor regulations) to—

(1) expand the public disclosure of Institutional Review Board (referred to as ''IRB'' in this section) deliberations, including summaries of key issues in submitted protocols and summary bases of decisions;

(2) maintain the confidentiality of protected health information, commercial confidential data, and trade secrets in such disclosures of IRB deliberations; and

(3) implement such disclosures, to the extent practicable, through the ClinicalTrials.gov website (or a successor website) maintained by the National Library of Medicine.

(c) BIORESEARCH MONITORING CAPACITY.—The Commissioner of Food and Drugs shall expand and enhance the bioresearch monitoring capacity of the Food and Drug Administration through the performance commitments under section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2).

SEC. 107. UPDATES TO PATIENT COSTS AND PAYMENT FOR PARTICIPATION IN CLINICAL TRIALS.

(a) ENABLING COVERAGE OF PATIENT COSTS AND USE OF EVIDENCE.—

(1) ROUTINE CARE COST COVERAGE CLARIFICATION.—

(A) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall issue guidance, or update the National Coverage Determination for Routine Costs in Clinical Trials, to clarify that a routine point-of-care clinical trial is a qualifying clinical trial, such that coverage is available under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for routine costs incurred in connection with such trial, including items and services furnished in connection with such trial through digital health tools and through providers operating in digital-first or remote care modalities.

(B) ALIGNMENTS WITH DATA STANDARDS.—The Administrator shall align the Centers for Medicare & Medicaid Services quality

measurement initiatives with the data standards established under section 105.

(2) POINT-OF-CARE EVIDENCE FOR COVERAGE GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Administrator shall issue or update guidance on how evidence from a routine point-of-care clinical trial may be applied to—

(A) national coverage determinations (as defined in section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B))) and updates thereto; and

(B) coverage of items and services subject to conditions of evidence development established by the Secretary under section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1395y(a)(1)(A)), commonly referred to as coverage with evidence development.

(b) CLINICAL TRIAL PARTICIPANT PAYMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Commissioner of Food and Drugs and the Director of the Office of Human Research Protections shall issue such rules as may be necessary with respect to compensation for participants in a clinical trial as to ensure compensation is commensurate

with the risks and burdens associated with the research and are not construed as constituting potential undue influence.

(c) CLINICAL TRIAL SITE PARTICIPANT PAYMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Commissioner of Food and Drugs and the Director of the National Institutes of Health, shall issue such rules as may be necessary with respect to fair compensation for site participants in a clinical trial.

TITLE II—MODERNIZED PRECLINICAL AND EARLY-STAGE CLINICAL DEVELOPMENT

SEC. 201. MODERNIZED EVIDENCE GENERATION THROUGH NEW APPROACH METHODOLOGIES.

(a) GUIDANCE FOR IMPLEMENTATION OF NEW APPROACH METHODOLOGIES.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, (in this section referred to as the ''Commissioner'') shall issue guidance and evidence frameworks, including through amending existing guidance or frameworks, to facilitate the implementation of new

approach methodologies for the purpose of streamlining and accelerating—

(A) preclinical pharmacology and toxicology studies;

(B) submission of investigational new drug applications; and

(C) early clinical phases of drug development.

(2) CONTENTS.—In issuing guidance under paragraph (1), the Commissioner shall—

(A) identify leading and novel use cases for in vitro and in silico technology, including by—

(i) expanding on streamlined nonclinical programs and acceptable new approach methodologies;

(ii) describing additional opportunities to apply such technology to toxicology;

(iii) describing how to validate complex in vitro and in silico technology as new approach methodologies; and

(iv) describing the use of human-derived in vitro and ex vivo systems where a nonclinical species does not express, or does not adequately recapitulate binding to, the human target of a targeted biologi-

cal product, including where a species-specific surrogate molecule would otherwise be required;

(B) implement pathways for the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research to validate new approach methodologies, for patients with a rare disease or other serious and life-threatening conditions, including the program established under section 507 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 357) and the plausible mechanism framework for rare diseases implemented by the Food and Drug Administration;

(C) incorporate—

(i) the information obtained through the workshops and meetings described in subsection (b); and

(ii) the policies established under subsection (c); and

(D) clarify the types and amount of data required to validate a new approach methodology for a context of use, and to expand such validated contexts of use.

(b) PUBLIC ENGAGEMENT.—The Commissioner, in consultation with the Director of the National Institutes of Health, shall hold workshops and public meetings to engage with sponsors, physicians, researchers, patients, and other stakeholders to, with respect to the development and validation of new approach methodologies, including in vitro and in silico technology—

(1) encourage pre-competitive collaboration between sponsors, researchers, technology developers, and preclinical research organizations;

(2) identify incentives for sponsor participation, including protection of intellectual property or such other proprietary protection, to encourage data sharing from completed preclinical projects; and

(3) advance collaborative analyses and validations of such methodologies to reduce development costs and increase the acceptance of such methodologies for preclinical testing and regulatory requirements, including by reducing or eliminating animal testing for new medical products.

(c) REGULATORY INNOVATION.—The Commissioner, in consultation with the Director of the National Institutes of Health and the Director of the Advanced Research Projects Agency–Health shall, using the information obtained through the workshops and meetings described in

subsection (b), establish a policy or platform for accelerated and precompetitive data sharing for, and analyses and validation of, new approach methodologies, that includes—

(1) an incentive for sponsor participation, including a method for regulatory validation of—

(A) digital and artificial intelligence tools;

(B) appropriate data security standards; and

(C) proprietary protection;

(2) a novel or improved validation method for a new approach methodology based on—

(A) data for such methodology; and

(B) traditional preclinical validation data for the clinical investigation of a medical product, regardless of whether such investigation proceeded to human studies;

(3) a sustainable method of funding, including—

(A) a sponsor applying to a Federal grant or contract program;;

(B) the Secretary establishing a Federal grant or contract program; or

(C) the Secretary recommending that Congress—

(i) establish a new Federal grant or contract program for the purposes described in this section; or

(ii) take other legislative action to establish such method of funding; and

(4) with respect to regulatory submissions, guidelines for enhanced collaboration with international regulatory authorities to advance the use and acceptance of a validated new approach methodology.

SEC. 202. MODERNIZED PHASE 1 CLINICAL TRIAL OVERSIGHT.

(a) IN GENERAL.—The Secretary shall establish an expedited procedure for review and initiation of lower-risk phase 1 trials, including through—

(1) issuing guidance, including through amending existing guidance; and

(2) establishing the pilot program under subsection (b).

(b) PILOT PROGRAM.—

(1) IN GENERAL.—The Secretary shall establish a pilot program for the third-party review of lower-risk phase 1 trials.

(2) QUALIFIED THIRD PARTIES.—

(A) CONSIDERATION AS QUALIFIED THIRD PARTY.—A third party is qualified to review a lower-risk phase 1 trial under the pilot program established under paragraph (1) if such third party—

(i) is—

(I) an institutional review board; or

(II) such other third party, as determined by the Secretary;

(ii) has technical competency to—

(I) review toxicology data; and

(II) ensure Chemistry, Manufacturing, and Controls (in this section referred to as ''CMC'') data is compliant with good manufacturing practices in a manner that is commensurate with any review carried out by the Commissioner of Foods and Drugs with respect to investigational new drug applications; and

(iii) complies with the criteria established under subparagraph (B).

(B) QUALIFICATION CRITERIA.—Using the criteria to accredit or deny accreditation to per-

sons who request to perform the duties specified in section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m) as a model, the Secretary shall establish criteria by which a third party may be considered a qualified third party under subparagraph (A)(iii).

(3) ESTABLISHMENT OF PILOT PROGRAM CRITERIA.—In carrying out the pilot program established under paragraph (1), the Secretary shall establish criteria for a qualified third party to review a lower-risk phase 1 trial, including the use of lead use cases and compliance with best practices for the effective, efficient, and timely ethical review and safety oversight of such trial.

(4) ENHANCED OVERSIGHT.—In carrying out the pilot program established under paragraph (1), the Secretary shall—

(A) collect performance data with respect to such pilot program;

(B) assess any review carried out under such pilot program to ensure that the quality of such review is commensurate with any review carried out by the Commissioner of Foods and Drugs with respect to investigational new drug applications; and

(C) audit any qualified third party who conducts such a review to assure program integrity.

(5) EXTENSION TO HIGHER-RISK PHASE 1 TRIALS.—The Secretary shall assess—

(A) any information obtained under paragraph (4); and

(B) the desirability of expanding such pilot program to include the review of higher-risk phase 1 trials by—

(i) establishing and piloting pre-certification standards with additional or enhanced requirements, as appropriate based on the risk of such trial, including for study conduct and monitoring, manufacturing, and adverse event mitigation;

(ii) developing specific guidance and pilot support for—

(I) a qualified institutional review board to review such a trial for a cell or gene therapy, or a gene editing product;

(II) clear and specific regulatory discussions for filing investigational new drug applications;

(III) CMC-readiness by a sponsor or investigator of such a trial; and

(IV) a dose escalation approach for such a trial; and

(iii) holding workshops, and publishing findings from such workshops, to support a potentially generalizable pre-certification process for early-stage studies of a cell or gene therapy, or a gene editing product.

(6) REGULATORY HARMONIZATION.—The Secretary shall assess whether subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulation), should be amended to ensure regulatory consistency with any information obtained under paragraphs (4) and (5).

(c) REQUIREMENTS WITH RESPECT TO ESTABLISHING EXPEDITED PROCEDURE.—For purposes of carrying out this section, the Secretary shall—

(1) establish criteria for classifying a phase 1 trial as a lower-risk phase 1 trial or a higher-risk phase 1 trial;

(2) assess relevant global regulatory programs with decentralized and expedited review and approval of phase 1 trials, including the Clinical Trial

Notification scheme established by the Parliament of Australia in the Therapeutic Goods Act 1989, and any amendments thereto; and

(3) incorporate any findings from such assessment into the expedited procedure established under subsection (a).

(d) APPROPRIATE MANUFACTURING STANDARDS.—

(1) PROPOSED RULE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue a proposed rule to revise such sections in title 21, Code of Federal Regulations, (or any successor regulations) relating to current good manufacturing practices for drugs, as may be necessary to ensure that, for an unapproved new drug or investigational drug intended for use in a lower-risk phase 1 trial, the burden of complying with CMC does not unnecessarily impede the initiation of such trial.

(2) CONSIDERATIONS.—In determining whether to revise a regulation under paragraph (1), the Secretary shall consider—

(A) the criteria established under subsection (c)(1);

(B) the risk associated with lower-risk phase 1 trials;

(C) the limited number of patients typically enrolled in phase 1 trials;

(D) the use of small-batch, non-continuous manufacturing processes;

(E) the clinical setting of lower-risk phase 1 trials, including—

(i) academic medical centers; or

(ii) in the case of routine point-of-care clinical trials, primary care and outpatient care settings; and

(F) the extent to which guidance for investigational drugs intended for use in lower-risk phase 1 trials can be included in regulation to provide greater regulatory certainty.

(3) FINAL RULE.—Not later than 1 year after the date on which the comment period ends for the proposed rule issued under paragraph (1), the Secretary shall—

(A) incorporate any information obtained under subsection (b)(4); and

(B) finalize such rule.

(e) DEFINITIONS.—In this section:

(1) HIGHER-RISK PHASE 1 TRIAL.—The term ''higher-risk phase 1 trial'' means a phase 1 trial—

(A) of an investigational drug that is intended to result in, or is capable of resulting in, modification of the genome of a human cell, including by integration, insertion, deletion, or base or prime editing;

(B) of an investigational drug that is replication-competent or capable of horizontal transfer;

(C) of an investigational drug the biological activity of which cannot be discontinued by cessation of dosing;

(D) of an investigational drug intended to produce sustained engagement of immune effector cells with an antigen expressed on essential non-malignant human tissue;

(E) of an investigational drug for which any prior clinical investigation has been placed on clinical hold pursuant to section 312.42 of title 21, Code of Federal Regulations (or any successor regulation); or

(F) that is more likely to expose human subjects to an unreasonable and significant risk of illness or injury.

(2) LOWER-RISK PHASE 1 TRIAL.—The term ''lower-risk phase 1 trial'' means a phase 1 trial—

(A) that presents a minimal potential for harm to a patient;

(B) that is an exploratory or phase 0 study of subtherapeutic or non-toxic doses with no therapeutic intent; or

(C) that is a study initiated by an investigator.

(3) PHASE 1 TRIAL.—The term ''phase 1 trial'' means phase 1 of a clinical investigation of a previously untested drug, as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

SEC. 203. GLOBAL REGULATORY ALIGNMENT TO MODERNIZE CLINICAL DEVELOPMENT.

(a) IN GENERAL.—Section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking '', and'' and inserting a semicolon;

(B) by redesignating paragraph (2) as paragraph (4); and

(C) by adding after paragraph (1) the following:

''(2) the standard, entitled 'Good Clinical Practice', maintained by the International Council for Harmonisation;''; and

(2) by adding at the end the following:

''(d)(1) The Secretary shall expand and coordinate efforts, including through enhanced international collaboration, to ensure compliance with the standard, entitled 'Good Clinical Practice', maintained by the International Council for Harmonisation for clinical trials conducted outside the United States.

''(2) The Secretary shall, in consultation with relevant nations and the International Council for Harmonisation, foster global regulatory alignment to modernize clinical early-stage medical product development, integrate real world data and digital health information into clinical investigations, and assure regulatory acceptance of investigations conducted by clinical trial networks embedded in routine practice.''.

(b) ENHANCING DATA INTEGRITY AND OVERSIGHT OF CLINICAL TRIALS AT SITES OF CONCERN.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following:

''(i)(1) With respect to an owner, operator, or agent in charge of an establishment carrying out a clinical inves-

tigation intended to support an application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall, as part of the inspection of such establishment under this section—

''(A) require such owner, operator, or agent to pre-certify that such clinical investigation complies with the standard, entitled 'Good Clinical Practice', maintained by the International Council for Harmonisation; and

''(B) verify, on-site or remotely, that, prior to the acceptance of data from any clinical trial site, contract research organization, or data management vendor that meets the criteria of a biotechnology company of concern (as defined in section 851(f)(2) of the National Defense Authorization Act for Fiscal Year 2026 (Public Law 119–60)), such clinical investigation complies with—

''(i) such standard; and

''(ii) data security protocols.

''(2) The Secretary may require an owner, operator, or agent described in paragraph (1) to pay a fee to cover any cost related to the activities described in such paragraph.''.

(c) STRENGTHENING FOREIGN EARLY-PHASE DATA VERIFICATION.—

(1) DOCUMENTATION REQUIREMENT.—The Secretary may, with respect to any patient-level data from a phase 1 or phase 2 clinical investigation conducted outside of the United States, require a sponsor or investigator to submit documentation of such patient-level data for purposes of ensuring the integrity of such investigation, such as—

(A) source data and audit trails for each primary or secondary endpoint tested in such investigation;

(B) records of informed consent, translated into English;

(C) the chain of custody for each biological sample and test article used in such investigation; and

(D) other documentation as deemed necessary by the Secretary.

(2) REFUSAL OF DATA.—The Secretary may refuse to accept such patient-level data if a sponsor or investigator does not comply with the requirement to provide documentation pursuant to paragraph (1).

(d) GUIDANCE ON DATA INTEGRITY AND INSPECTION ACCESS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall revise the

guidance issued by the Food and Drug Administration, entitled ''Guidance for Industry: Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'', (issued June 2024) to provide clarification on any action the Secretary will take if a person does not comply with any requirement established by the Secretary under section 704(i) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b) of this section.

SEC. 204. MINIMUM UNITED STATES REPRESENTATION IN CLINICAL TRIALS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall require that each pivotal study submitted in support of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) meet the requirements of subsection (b).

(b) U.S. PARTICIPATION.—A pivotal study contained in an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a))—

(1) may not be based solely on foreign clinical data;

(2) shall include patients enrolled at clinical investigation sites in the United States, including as part of a multi-national clinical trial to support such application;

(3) shall align with international harmonization efforts, including the guidance issued by the International Council for Harmonisation, entitled ''General Principles for Planning and Design of Multi-Regional Clinical Trials'' (E17; adopted November 16, 2017); and

(4) shall include any other evaluation metrics as determined by the Secretary, including if—

(A) the drug or biological product that is the subject of the application described in this Act is intended to treat a rare disease or condition;

(B) the Secretary determines that foreign clinical data—

(i) is derived from a clinical investigation conducted in accordance with good clinical practice;

(ii) is applicable to the United States population and United States medical practice; and

(iii) is validated through an on-site inspection of the relevant trial site or other appropriate means, as determined by the Secretary;

(C) clinical investigation sites in the United States are unavailable;

(D) establishing a clinical investigation site in the United States is otherwise impracticable; or

(E) a waiver is necessary to protect public health during a public health emergency.

SEC. 205. FOOD AND DRUG ADMINISTRATION RARE DISEASE INNOVATION HUB.

The Federal Food, Drug, and Cosmetic Act is amended by adding after section 1014 (21 U.S.C. 360ff–1) the following:

"SEC. 1014A. FOOD AND DRUG ADMINISTRATION RARE DISEASE INNOVATION HUB.

"(a) FOOD AND DRUG ADMINISTRATION RARE DISEASE INNOVATION HUB.—The Secretary shall establish the Food and Drug Administration Rare Disease Innovation Hub (in this section referred to as the 'Hub') as an Intercenter Institute described in section 1014 to—

"(1) advance regulatory science for a rare disease or condition;

''(2) provide technical assistance to review teams assessing rare disease medical products to ensure reviewer consistency and documentation of agreements upon acceptable trial designs;

''(3) promote innovation of rare disease medical products;

''(4) leverage lead networks (established in title I of the Faster Clinical Trials Act), interoperable technology and data infrastructure, and public-private collaboration mechanisms to advance natural history studies, distributed and platform clinical trials, biomarker and clinical outcome assessment development, and fit-for-purpose evidence generated from real-world data generation for rare diseases;

''(5) enhance coordination, alignment, and collaboration between the heads of the Directors listed in subsection (b)(1) and other Intercenter Institutes established under section 1014 with respect to the development and regulation of rare disease medical products;

''(6) foster and support dialogue and public-private partnerships with patients who have, and providers that treat, a rare disease or condition to ensure such development is patient-focused;

''(7) allow sponsors to consult with the Hub regarding questions, concerns, or deliberations throughout the review process; and

''(8) function as a point of escalation for sponsors of rare disease medical products to request review or consultation regarding review decisions.

''(b) ACTIVITIES.—In addition to the activities of an Intercenter Institute described in section 1014, the Hub shall—

''(1) facilitate collaboration, information sharing, regulatory consistency, and cross-disciplinary training and product reviews with—

''(A) the Office of Orphan Products Development;

''(B) the Center for Drug Evaluation and Research;

''(C) the Center for Biologics Evaluation and Research;

''(D) the Center for Devices and Radiological Health; and

''(E) the Oncology Center of Excellence; and

''(2) award grants, cooperative agreements, or contracts, or enter into memoranda of understanding, to—

''(A) support natural history studies, the use of novel clinical trial designs, and the application of the plausible mechanism evidentiary framework;

''(B) accelerate the development and validation of early and novel biomarkers and endpoints for rare diseases or conditions, pursuant to section 507 of this Act and section 3208 of the Food and Drug Omnibus Reform Act (Public Law 117–328);

''(C) ensure targeted technical assistance is provided for—

''(i) investigator-initiated clinical trials for medical products intended to treat rare diseases or conditions; and

''(ii) patient-sponsored development programs for such medical products;

''(D) hold meetings and workshops to engage directly with—

''(i) rare disease patient organizations and families of patients with rare diseases or conditions;

''(ii) developers of rare disease medical products; and

''(iii) researchers and specialty medical societies; and

''(E) assist in addressing scientific, clinical, and policy issues related to the development and regulation of such products.

''(c) PUBLIC-PRIVATE PARTNERSHIPS AND CONSORTIA.—The Hub shall foster public-private partnerships or consortia to support the activities required under this section, including initiatives to—

''(1) de-risk and facilitate access to manufacturing capacity, including at Federal laboratories and facilities, for—

''(A) investigator-initiated clinical trials for rare disease medical products; and

''(B) patient-sponsored development programs for such medical products; and

''(2) support clinical trials for, and development of, such a medical product through a national network of clinical centers of excellence for rare diseases or conditions.

''(d) REPORT.—Not later than 9 months after the date of enactment of this subsection, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and make

available to the public, a report containing recommendations on the development and regulation of a medical product intended to treat a rare disease or condition, including—

''(1) whether to selectively restore the establishment license application under section 351 of the Public Health Service Act (42 U.S.C. 262) to facilitate the manufacture of rare disease medical products by nontraditional sponsors; and

''(2) whether to enhance regulatory flexibility and manufacturing capacity for nontraditional sponsors, such as academic laboratories or patient organizations, of—

''(A) an investigator-initiated clinical trial for a rare disease medical product;

''(B) a patient-sponsored development program for such a medical product; and

''(C) research and development for medical products intended to treat or diagnose very rare and n-of-1 diseases or conditions.

''(e) FUNDING.—

''(1) IN GENERAL.—To carry out this section, the Secretary shall transfer to the Hub for each of fiscal years 2027 through 2031—

''(A) $5,000,000 from the amounts made available in the FDA Innovation Account under section 1002(b)(2)(A) of the 21st Century Cures Act (Public Law 114–255);

''(B) $10,000,000 from the amounts made available under section 481A of the Public Health Service Act (42 U.S.C. 287a–2) for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases; and

''(C) $15,000,000 from the amounts made available to carry out section 499A(f) of such Act (42 U.S.C. 290c(f)), related to cooperation of the Advanced Research Projects Agency–Health with the Food and Drug Administration to facilitate the development of medical products and projects that are the highest priorities to the Advanced Research Projects Agency–Health.

''(2) BUDGET CLARIFICATION.—Any budget request of the President shall specify an amount for carrying out this section.

''(f) DEFINITIONS.—In this section:

''(1) MEDICAL PRODUCT.—The term 'medical product' means—

''(A) a drug or device, as defined in section 201 of this Act; or

''(B) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

''(2) RARE DISEASE OR CONDITION.—The term 'rare disease or condition' has the meaning given such term in section 526.''.

TITLE III—ENHANCED FOOD AND DRUG ADMINISTRATION REGULATIONS TO SUPPORT INNOVATION

SEC. 301. RESOLVING CLINICAL HOLDS AND IMPROVING CLINICAL TRIAL EFFICIENCY.

(a) IN GENERAL.—For purposes of improving the efficiency and integrity of clinical investigations, the Secretary shall address any root cause of a clinical hold imposed under section 312.42 of title 21, Code of Federal Regulations (or any successor regulation), or the disapproval or withdrawal of approval of an investigational device exemption under section 812.30 of such title (or any successor regulation), including—

(1) identifying common sources of noncompliance with such regulations and common causes of clinical holds and development delays, with a focus

on first-time sponsors of a clinical trial and investigator-initiated clinical trials, IRBs, CROs and other experienced implementation and technology partners, research sites;

(2) developing and disseminating best practices for—

(A) compliance with good clinical practices;

(B) efficient development, filing, and review of investigational new drug applications and investigational device exemptions; and

(C) increasing the frequency and documentation of in-person meetings for sponsors of investigational new drug applications and investigational device exemptions in lieu of written responses to provide specific, authoritative, and consistent guidance with a focus on action items and enhancements;

(3) early and additional sponsor engagement consistent with, and additive to, the performance commitments under section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) to—

(A) secure rapid alignment on a trial design in support of a complete application for a proposed indication of use; and

(B) create additional opportunities for informal, rapid feedback to such a sponsor, including science-focused drug development meetings;

(4) increasing the use of external advisory committees;

(5) early and consistent integration of staff with requisite expertise in rare diseases or conditions, as appropriate, in review teams for the review of investigational and premarket new drug applications;

(6) clarifying what information qualifies to be redacted when disclosing complete response letters to the public;

(7) revising procedures and guidance for—

(A) clarifying what information must be redacted when publicly disclosing complete response letters and other investigational and premarket new drug application materials to the public;

(B) developing and publicly disclosing novel redaction methods and tools, including automation or artificial intelligence;

(C) the timely public disclosure of complete response letters and other investigational and premarket new drug application materials; and

(D) the establishment of pilot programs to facilitate timely public access to such letters and such application materials; and

(8) creating a designated Food and Drug Administration contact for process and regulatory-navigation questions for emerging biotechnology companies.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $500,000,000 for each of the fiscal years 2027 through 2031, to remain available until expended.

SEC. 302. MUTUAL RECOGNITION OF GMP STANDARDS.

(a) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking ''and'' at the end;

(B) in paragraph (3), by striking the period at the end and inserting ''; and''; and

(C) by inserting after paragraph (3) the following:

''(4) shall implement a procedure for exchanging inspection reports with a foreign government or an agency of a foreign government that the Secretary has entered into an arrangement or agreement with under this section to avoid duplicating an inspection in which a foreign establishment registered under section 510 was found to be in compliance with good manufacturing practice regulations promulgated under section 501.'';

(2) by redesignating subsection (c) as subsection (d);

(3) by inserting after subsection (b) the following:

''(c) RISK-BASED PRIORITIZATION PLAN.—For purposes of increasing the rate of inspections, the Secretary shall implement a plan for the use of risk-based prioritization for inspections of establishments registered under section 510, which shall include consideration of—

''(1) the history of such an establishment with respect to complying with good manufacturing practice regulations promulgated under section 520(f);

''(2) the inherent risk of the drug or device manufactured, prepared, propagated, compounded, or processed (as defined in section 510) at such establishment; and

''(3) the availability of recent inspection reports from a foreign government or an agency of a foreign government that the Secretary has entered into an arrangement or agreement with under this section.''; and

(4) in paragraph (2) of subsection (d), as redesignated by paragraph (2) of this section—

(A) by striking ''Beginning not later'' and inserting the following:

''(A) IN GENERAL.—Beginning not later''; and

(B) by adding at the end the following:

''(B) REPORTING ON MUTUAL RECOGNITION.—The report under subparagraph (A) shall include, with respect to the period covered by the report an update on the status of any agreement the Secretary enters into with a foreign country under section 803 related to encouraging the mutual recognition of good manufacturing practice regulations promulgated under section 520(f) with respect to inspections.''.

(b) EXPANSION OF MUTUAL RECOGNITION AGREEMENTS TO BIORESEARCH MONITORING.—Section 803(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

383(b)) is amended by inserting after paragraph (2), as inserted by section 203(a)(1)(C), the following:

''(3) the bioresearch monitoring program implemented by the Food and Drug Administration through compliance programs shall identify ways to—

''(A) allow such countries to rely on any inspection conducted by the Food and Drug Administration related to an establishment performing clinical research;

''(B) reduce the regulatory burden on such an establishment in the United States; and

''(C) provide the Secretary with maximum flexibility to focus resources related to inspections and compliance on establishments that pose the greatest risk to data integrity or safety.''.

SEC. 303. PATHWAY FOR COMPETITIVE GENERIC THERAPIES.

(a) REVIEW.—The Secretary shall review and provide recommendations to improve the pathway for competitive generic therapies established pursuant to section 506H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356h) no later than 12 months after the date of the enactment of this Act.

(b) IMPROVEMENT.—Following the review under paragraph (1), the Secretary shall—

(1) report the review, its findings, and any recommendations to committees of jurisdiction within 12 months of the date of the enactment of this Act; and

(2) not later than 6 months after transmitting the review to Congress, begin implementing the recommendations.

(c) COLLABORATION.—In carrying out this section, the Secretary shall incorporate the perspectives of health care stakeholders.

SEC. 304. BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended—

(1) in the subsection heading, by striking ''OR INTERCHANGEABLE'';

(2) in paragraph (2)—

(A) by striking subparagraph (B);

(B) by redesignating clauses (ii) and (iii) of subparagraph (A) as subparagraphs (B) and (C), respectively, and adjusting the margins accordingly;

(C) in subparagraph (A)—

(i) in clause (i), by redesignating subclauses (I) through (V) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (i), as so redesignated by clause (i) of this subparagraph, by redesignating items (aa) through (cc) as subclauses (I) through (III), respectively, and adjusting the margins accordingly;

(iii) in subclause (II) of clause (i), as so redesignated by clause (ii) of this subparagraph, by striking ''item (aa) or (cc)'' and inserting ''subclause (I) or (III)''; and

(iv) by striking ''(A) IN GENERAL'' and all that follows through ''An application submitted under this subsection shall include information'' and inserting the following:

''(A) IN GENERAL.—An application submitted under this subsection shall include information'';

(D) in subparagraph (B), as so redesignated by subparagraph (B) of this paragraph, by striking ''clause (i)(I)'' and inserting ''subparagraph (A)(i)''; and

(E) in subparagraph (C), as so redesignated by subparagraph (B) of this paragraph, by redesignating subclauses (I) through (III) as clauses (i) through (iii), respectively, and adjusting the margins accordingly;

(3) by amending subparagraph (A) of paragraph (3) to read as follows:

''(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product is biosimilar to the reference product; and'';

(4) by amending paragraph (4) to read as follows:

''(4) INTERCHANGEABILITY.—

''(A) IN GENERAL.—A biological product licensed under this subsection shall be deemed to be interchangeable with the reference product, subject to subparagraph (B).

''(B) TIMING OF DEEMED INTERCHANGEABILITY.—

''(i) LICENSURE ON OR AFTER TRANSITION DATE.—A biological product licensed under this subsection on or after the transition date described in subpara-

graph (C) (in this clause referred to as the 'applicable biological product') shall be deemed to be interchangeable with the reference product upon such licensure, unless the applicable biological product relied on the same reference product as another biological product for which—

''(I) licensure under this subsection was in effect on the day before the date of enactment of the Faster Clinical Trials Act; and

''(II) a first interchangeable exclusivity period under paragraph (6) (as in effect on the day before the date of enactment of such Act) is in effect on the date of licensure of the applicable biological product,

in which case the applicable biological product shall be deemed interchangeable with the reference product under this paragraph on the date on which the exclusivity period described in subclause (II) ends.

''(ii) LICENSURE PRIOR TO TRANSITION DATE.—A biological product licensed under this subsection prior to the transi-

tion date described in subparagraph (C) (referred to in this clause as the 'applicable biological product') shall be deemed to be interchangeable with the reference product on such transition date, unless the applicable biological product relied on the same reference product as another biological product for which—

''(I) licensure under this subsection was in effect on the day before the date of enactment of the Faster Clinical Trials Act; and

''(II) a first interchangeable exclusivity period under paragraph (6) (as in effect on the day before the date of enactment of such Act) is in effect on the transition date,

in which case the applicable biological product shall be deemed interchangeable with the reference product under this paragraph on the date on which the exclusivity period described in subclause (II) ends.

''(C) TRANSITION DATE.—The transition date described in this subparagraph is the date

that is 60 days after the date of enactment of the Faster Clinical Trials Act.'';

(5) by amending paragraph (6) to read as follows:

''(6) TRANSITION WITH RESPECT TO PRESERVING FIRST INTERCHANGEABLE EXCLUSIVITY WITH RESPECT TO CERTAIN BIOLOGICAL PRODUCTS.—With respect to a biological product licensed under this subsection before the date of enactment of the Faster Clinical Trials Act, for which there was an unexpired period of first interchangeable exclusivity under this subsection (as then in effect), such unexpired exclusivity period shall remain in effect for the duration of such period.''; and

(6) in paragraph (8)(D)—

(A) in clause (i), by striking ''class; and'' and inserting ''class.'';

(B) by striking clause (ii); and

(C) by striking ''description of—'' and all that follows through ''criteria that the Secretary'' and inserting ''description of the criteria that the Secretary''.

(b) CONFORMING AMENDMENTS.—

(1) Section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)) is amended by striking

''that is shown to meet the standards described in subsection (k)(4)'' and inserting ''licensed under subsection (k)''.

(2) Section 352A of the Public Health Service Act (42 U.S.C. 263–1) is amended by striking ''and interchangeable biosimilar biological products'' each place such term appears.

(3) Section 744G(14) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(14)) is amended by striking '', including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act''.

(4) Section 505B(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(l)) is amended to read as follows:

''(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biological product for which an application is submitted under section 351(k) of the Public Health Service Act shall be considered to have a new active ingredient for purposes of this section only if—

''(1) the application seeks licensure for a claimed indication—

''(A) that has been approved for a relevant pediatric population; or

''(B) for which there is a deferral of a relevant pediatric assessment under subsection (a)(4) of this section for the reference product applicant; and

''(2) a pediatric assessment under this section would not involve the development of a biological product with a strength, dosage form, route of administration, and condition of use for which there would not be a reference product.''.

(c) GUIDANCE.—The Secretary shall—

(1) not later than 18 months after the date of enactment of this Act, update existing draft and final guidance to reflect the amendments made by this section, including by revising or revoking the guidance entitled ''Considerations in Demonstrating Interchangeability With a Reference Product'' (May 2019) and ''Considerations in Demonstrating Interchangeability With a Reference Product: Update'' (June 2024);

(2) not later than 18 months after the date of enactment of this Act, issue or revise guidance on review and approval of biosimilar biological products under section 351(k) of the Public Health Service

Act (42 U.S.C. 262(k)) relating to the data and information that an applicant is required to submit to support a determination that a biosimilar biological product that is the subject of an application under such section is biosimilar to the reference product (as defined in section 351(i) of such Act (42 U.S.C. 262(i))); and

(3) not later than 18 months after the comment period closes on the guidance under paragraphs (1) and (2), issue revised draft or final versions of such guidance.

(d) RULE OF CONSTRUCTION.—The amendments made by this section shall not be construed—

(1) to alter the standard or the information required for licensure of a biological product as biosimilar to a reference product pursuant to section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); or

(2) to limit the information that may be required by the Secretary to support the licensure of a biological product as biosimilar to a reference product pursuant to such section.

SEC. 305. CERTIFICATION OF PATENT INFORMATION IN CERTAIN APPLICATIONS FOR BIOLOGICAL PRODUCTS.

Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(o) CERTIFICATION OF PATENT INFORMATION IN CERTAIN APPLICATIONS.—

''(1) IN GENERAL.—An application submitted under this section for a biological product that includes a full report of a covered investigation shall also include—

''(A) a certification, in the opinion of the applicant and to the best of their knowledge, with respect to each covered patent—

''(i) that such patent information has not been filed;

''(ii) that such patent has expired;

''(iii) of the date on which such patent will expire; or

''(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of such product for which the application is submitted; and

''(B) if information was filed under subsection (l) for a method of use patent which

does not claim a use for which the applicant is seeking approval under this section, a statement that the method of use patent does not claim such a use.

''(2) DEFINITIONS.—In this subsection:

''(A) COVERED INVESTIGATION.—The term 'covered investigation' means, with respect to a biological product for which an applicant submitted an application under this section, an investigation of such product that—

''(i) was conducted to demonstrate whether such product is safe for use and is effective in use;

''(ii) was not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigation was conducted; and

''(iii) is relied upon by the applicant seeking approval of such application.

''(B) COVERED PATENT.—The term 'covered patent' means a patent—

''(i) which claims—

''(I) the biological product for which a covered investigation was conducted; or

''(II) a use for such product for which an applicant is seeking approval of an application under this section; and

''(ii) for which information is required to be filed under subsection (l).''.

SEC. 306. GAO REPORT.

Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report evaluating—

(1) any progress in implementing section 301 during the period covered by the report;

(2) dissemination by the Food and Drug Administration of resources related to developing a drug;

(3) implementation by the Secretary of pilot programs using fees made available pursuant to subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.), such as the Split Real Time Application Review pilot program, the Model-Informed Drug Development Paired Meeting Program, and the Chemistry, Manu-

facturing, and Controls Development and Readiness Pilot Program;

(4) implementation by the Secretary of each program established by this Act or an amendment made by this Act to improve clinical trial efficiency and ensure regulatory consistency; and

(5) whether implementing each such program has had a beneficial impact on the development of a medical product for a rare disease or condition, including a rare cancer.

SEC. 307. DEFINITIONS.

In this Act:

(1) CLINICAL INVESTIGATION.—The term ''clinical investigation'' has the meaning given such term in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation).

(2) DEPARTMENT.—The term ''Department'' means the Department of Health and Human Services.

(3) GOOD CLINICAL PRACTICE.—The term ''good clinical practice'' means the standard, entitled ''Good Clinical Practice'', maintained by the International Council for Harmonisation and implemented by the Secretary.

(4) INSTITUTIONAL REVIEW BOARD.—The terms ''institutional review board'' has the meaning given such term in section 56.102 of title 21, Code of Federal Regulations (or any successor regulation).

(5) INVESTIGATIONAL NEW DRUG APPLICATION.—The term ''investigational new drug application'' means an application submitted pursuant to part 312 of title 21, Code of Federal Regulations (or any successor regulation) for an investigational new drug (as defined in section 312.3 of such part).

(6) MEDICAL PRODUCT.—The term ''medical product'' means—

(A) a drug or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(B) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

(7) RARE DISEASE OR CONDITION.—The term ''rare disease or condition'' has the meaning given such term in section 526(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)).

(8) ROUTINE POINT-OF-CARE CLINICAL TRIAL.—The term ''routine point-of-care clinical

trial'' means a clinical investigation of a medical product that—

(A) is integrated into clinical practice, including routine in-person, or virtual, visits;

(B) includes health providers as investigators;

(C) may be conducted in a primary care setting, an outpatient care setting, the home of a patient participating in such investigation, or a similar location; and

(D) may follow a streamlined protocol and procedures focused on essential data collection generating or incorporating real-world data from an electronic or other health record.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE IV—PRECISION ONCOLOGY MODERNIZATION

SEC. 401. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds the following:

(1) Advances in molecular oncology have enabled the identification of specific genetic alterations that drive certain cancers, enabling the development of targeted therapies with high efficacy in defined patient populations.

(2) Approved oncology drug labels frequently reflect clinical trial populations that predate the routine use of genomic profiling and may not adequately reflect current scientific understanding of patient subpopulations for whom a given therapy is inappropriate.

(3) Outdated labeling can contribute to suboptimal treatment sequencing, unnecessary toxicity, and foregone opportunity for patients to receive a more precisely and effective targeted treatment option.

(4) The Food and Drug Administration's Project Renewal initiative, established to modernize drug product labeling to reflect contemporary scientific and clinical knowledge, provides a foundation that can be expanded to systematically address genomic exclusions in oncology drug labels.

(5) A formal, science-driven process for incorporating genomic exclusion criteria into oncology labeling would promote precision medicine, improve patient outcomes, and advance the efficient use of healthcare resources.

(b) PURPOSE.—To establish a process for reviewing and updating the labeling of approved oncology drugs to reflect genetically defined patient subpopulations.

SEC. 402. ONCOLOGY CENTER OF EXCELLENCE.

(a) IN GENERAL.—The Secretary shall establish the Food and Drug Administration Oncology Center of Excellence as an Intercenter Institute described in section 1014 to promote development and facilitate the review of medical products intended to diagnose and treat oncologic and hematologic malignancies, including—

(1) cancers in infants, children and adolescents; and

(2) rare cancers.

(b) ACTIVITIES.—In addition to the activities of an Intercenter Institute described in section 1014, the Oncology Center of Excellence shall—

(1) sponsor or conduct projects to advance the development and regulation of medical products for patients with cancer, including—

(A) Project Orbis a collaborative framework to facilitate the concurrent submission and collaborative regulatory review of oncology products among international regulatory authorities to expedite global patient access to safe and effective cancer treatments;

(B) Project Optimus a program to reform dose optimization and selection for oncologic therapies by encouraging multi-dose characterization early in clinical development;

(C) Real-Time Oncology Review (RTOR) a voluntary pilot program for the early submission of data modules prior to the formal filing of a complete oncology marketing application to streamline regulatory review;

(D) Project Confirm a public framework for the monitoring of confirmatory clinical trials required under the accelerated approval pathway for oncology indications to track the confirmation of clinical benefit;

(E) Project Pragmatica a program to integrate pragmatic clinical trial designs into the evaluation of approved oncology medical products, utilizing streamlined eligibility criteria and real-world clinical practice settings to reduce operational burdens on patients and investigators; and

(F) Project Renewal a program to assess information that may inform updates to the labeling of oncology drugs to incorporate genomic exclusion criteria; and

(2) assist in addressing scientific, clinical, and policy issues related to the development and regulation of oncology and hematology products;

(3) award grants, cooperative agreements, or contracts, or enter into memoranda of understanding, and foster public-private partnerships or consortia to support the activities required under this section; and

(4) hold meetings and workshops to engage directly with—

(A) cancer patient organizations and families of patients with cancer;

(B) developers of oncology and hematology products; and

(C) researchers and specialty medical societies.

(c) FUNDING.—

(1) IN GENERAL.—To carry out this section, the Secretary shall transfer to the Oncology Center of Excellence for each of fiscal years 2027 through 2031—

(A) such sums as necessary from the amounts made available in the FDA Innovation Account under section 1002(b)(2)(A) of the 21st Century Cures Act (Public Law 114–255);

(B) such sums as necessary from amounts made available pursuant to interagency transfers and agreements, including with the Na-

tional Cancer Institute, as authorized under 31 U.S.C. 1535; and

(C) such sums as necessary from the amounts made available to carry out section 499A(f) of such Act (42 U.S.C. 290c(f)), related to cooperation of the Advanced Research Projects Agency–Health with the Food and Drug Administration to facilitate the development of medical products and projects that are the highest priorities to the Advanced Research Projects Agency–Health.

(2) BUDGET CLARIFICATION.—Any budget request of the President shall specify an amount for carrying out this section.

SEC. 403. LABELING REVISIONS FOR GENOMIC EXCLUSIONS IN ONCOLOGY DRUGS.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary shall establish, acting through the Food and Drug Administration Oncology Center of Excellence (hereinafter referred to as the ''Center'', a program to assess information that may inform updates to the labeling of approved oncology drugs to incorporate genomic exclusion criteria (hereinafter referred to as the ''Program'').

(b) DUTIES.—In carrying out the Program, the Center shall—

(1) identify oncology drugs approved under 505(b) or 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b) or (j)), or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) for which—

(A) there is new scientific evidence available pertaining to one or more actionable genetic alterations that is not reflected in the approved labeling of such drugs; and

(B) the updating of such approved labeling would benefit the public health; and

(2) establish a process to—

(A) identify such drugs, including—

(i) the procedures authorized under section 503D(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 353d(b)), to receive clinical evidence on the impact of actionable genetic alterations on patient outcomes; and

(ii) engagement through meetings and workshops authorized under section 3(b)(4) with—

(I) holders of approved oncology drug applications and other drug sponsors;

(II) the Food and Drug Administation Rare Disease Innovation Hub;

(III) the National Cancer Institute; and

(IV) patient advocacy organizations, oncology professional societies, diagnostic test developers, and other relevant stakeholders;

(B) develop standardized language for genomic exclusion criteria to support clear statements regarding the additional, modified, or supplemental information for amended oncology drug labeling;

(C) encourage holders of approved oncology drug applications to submit voluntary labeling supplements to incorporate genomic exclusion criteria, including as supplemental applications described in sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations); and

(D) initiate labeling changes to incorporate genomic exclusion criteria, including under section 505(o) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(o)) and in a manner consistent with the requirements of section 503D(f)(2) of the Federal Food, Drug and Cosmetic Act (Act (21 U.S.C. 353D(f)(2)).

(c) SELECTION OF ONCOLOGY DRUGS.—The Center shall identify oncology drugs under this section—

(1) based on factors including—

(A) the strength and consistency of clinical evidence supporting the impact of the action genetic alteration on patient outcomes;

(B) the availability of one or more approved targeted oncology therapies addressing the relevant actionable genetic alteration or oncogenic driver;

(C) the prevalence of the relevant genetic alteration or oncogenic driver in the indicated patient population; and

(D) the potential clinical impact of failing to identify and exclude patients with the relevant alteration;

(2) on the basis of the available scientific evidence for incorporating genomic exclusion criteria

into oncology drug labeling that meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the identified drug, including—

(A) data from randomized controlled trials demonstrating reduced effectiveness or safety changes of approved oncology products for patients with specific actionable genetic alterations;

(B) prospective or retrospective biomarker analyses from adequate and well-controlled studies;

(C) real-world evidence; and

(D) mechanistic or preclinical evidence in conjunction with clinical data, where appropriate; and

(3) with consideration given to—

(A) whether a companion diagnostic test approved or cleared under section 515 or section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e and 21 U.S.C. 360(k)) respectively, or a laboratory developed test, is necessary to identify patients with a relevant actionable genetic alteration prior to seek-

ing or initiating a labeling change to incorporate a genomic exclusion criterion into labeling under subsection (b);

(B) promoting alignment, in coordination with the Center for Devices and Radiological Health, as appropriate, between revised oncology drug labeling under this section and the labeling of approved or cleared companion diagnostics; and

(C) utilization of genomic profiling under next-generation sequencing or other multi-gene testing as a basis for identifying patients subject to a genomic exclusion criterion.

(e) EXPEDITED REVIEW FOR LABELING SUPPLEMENTS.—Labeling supplements to incorporate genomic exclusion criteria submitted pursuant to 505(xx) or 505(o)(4) shall—

(1) be exempt from user fees under the Prescription Drug User Fee Act; and

(2) be reviewed and acted upon no later than 180 days after submission of a complete supplement.

Nothing in this subsection shall be constructed to limit the processes outlined in 505(o)(4).

(f) TRANSPARENCY AND PUBLIC ACCESS.—The Secretary shall—

(1) maintain and make publicly available on the Food and Drug Administration's website a registry of oncology drug labels updated under the Program, and the evidence basis for each genomic exclusion determination;

(2) publish, not less frequently than annually, a report summarizing Program activities, labeling updates completed, supplements received and acted upon, and any anticipated genetic alterations under consideration for the following year; and

(g) GUIDANCE.—Within 180 days of enactment of the Precision Oncology Modernization Act, the Secretary shall issue draft guidance on the actions described in subsection (b), standards in subsection (c), and role of CDRH outlined in subsection (d). The guidance shall be finalized no later than 2 years after enactment.

(h) REPORT TO CONGRESS.—Not later than 3 years after the date of enactment of this Act, and every 2 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that includes—

(1) a description of the activities carried out under the Program, including the number of oncol-

ogy drug labels reviewed, updated, or pending update;

(2) the number of voluntary labeling supplements received and acted upon under the Program;

(3) an assessment of challenges and barriers encountered in implementing the Program, including any scientific, legal, or operational barriers;

(4) recommendations for legislative or regulatory changes that would improve the Program or accelerate the incorporation of genomic exclusion criteria into oncology drug labeling; and

(5) an analysis of the potential impact of Program activities on patient outcomes, treatment sequencing, and access to targeted oncology therapies.

(i) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed—

(1) to limit the authority of the Secretary to require labeling changes for approved drugs under any other provision of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act;

(2) to affect the approval status of any oncology drug or biological product approved before the date of enactment of this Act except with respect to labeling updates made pursuant to the Program.

The rules of construction under section 503D(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353d(b)) shall be deemed to apply to this section.

(j) DEFINITIONS.—In this Act:

(1) ACTIONABLE GENETIC ALTERATION.—The term ''actionable genetic alteration'' means a somatic or germline mutation, gene fusion, copy number variation, or other molecular aberration in a patient's tumor or germline that has been demonstrated through clinical evidence to predict a meaningful difference in response or resistance that impacts the safety or efficacy of a drug or biological product intended to treat cancer.

(2) APPROVED TARGETED ONCOLOGY THERAPY.—The term ''approved targeted oncology therapy'' means a drug or biological product approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the treatment of a cancer defined in whole or in part by the presence of a specific genetic alteration.

(3) GENOMIC EXCLUSION CRITERION.—The term ''genomic exclusion criterion'' means a labeling statement specifying that a drug is not indicated for, or should not be used in, patients whose tumors har-

bor a specific actionable genetic alteration for which an alternative approved targeted oncology therapy exists.

TITLE V—AMERICAN FRONTIER BIOBANK

SEC. 501. ESTABLISHMENT OF THE AMERICAN FRONTIER BIOBANK.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281et seq.) is amended by adding at the end following:

"SEC. 404P. AMERICAN FRONTIER BIOBANK.

''(a) IN GENERAL.—Pursuant to section 498E, the Director of NIH shall carry out a program to be known as the 'American Frontier Biobank Program' (referred to in this section as the 'Biobank Program'), which shall expand upon the work of the All of Us Research Program.

''(b) TRANSITION.—Not later than 6 months after the date of the enactment of this section, the Director of NIH shall—

''(1) transfer to the Biobank Program, the authorities (including all budget authorities, available appropriations, and personnel), duties, obligations, and related legal and administrative functions, and the existing cohort, data, computational infrastruc-

ture, and biobanking capabilities of the All of Us Research Program; and

''(2) provide for the orderly transition or realignment of awards made under, and capabilities of, the All of Us Research Program.

''(c) ADMINISTRATOR.—The Biobank Program shall be headed by an Administrator appointed by the Director of NIH. Such person shall be known and referred to as the American Frontier Biobank Administrator (in this section referred to as the 'Administrator').

''(d) PROGRAM ELEMENTS.—In carrying out the Biobank Program, the Administrator shall—

''(1) make awards to, or enter into contracts with, corporate entities or non-profit entities across the United States to facilitate—

''(A) the collection, storage, molecular data generation, and analysis of biological specimens, including longitudinal molecular and clinical data; and

''(B) with the support of artificial intelligence and other technologies, as appropriate, incorporating electronic health records of participants in accordance with subsection (c);

''(2) facilitate the recruitment of participants that are representative of at least 3 percent of the

United States population, including representation of each State of the United States, the District of Columbia, each commonwealth, territory or possession of the United States, and each federally recognized Indian Tribe, with longitudinal data gathered in both urban and rural populations, including a pediatric cohort of participants;

''(3) in facilitating the recruitment of participants under paragraph (2) who are members of a federally recognized Indian Tribe, work in partnership with Tribal nations, and through Tribal consultation, to establish mutually agreeable terms for Tribal participation, and operational processes and oversight, that respect Tribal sovereignty;

''(4) enter into data sharing agreements with private and non-profit entities to build upon existing processes for the rapid, cost-effective, and scalable recruitment, and enrollment of, and obtaining informed consent from, participants for the collection of longitudinal data;

''(5) seek to enroll in clinical trials, using data in the Biobank, the individuals whose biological specimens are stored in the Biobank;

''(6) share deidentified data collected for the Biobank Program with all registered researchers;

''(7) incorporate existing data sources of the National Institutes of Health, and other relevant datasets (as determined by the Administrator into research activities conducted through the Biobank Program, including data collected through the All of Us initiative and the Department of Veterans Affairs Millions Veterans Program;

''(8) generate and integrate multi-modal data, including genomic, proteomic, metabolomic, and other molecular data, with electronic health records and participant-reported information;

''(9) enable longitudinal participant data collection, including by conducting repeat sampling, engaging in continuous health data integration, and developing scalable research infrastructure to reduce the long-term costs of biomedical research and healthcare innovation;

''(10) support artificial intelligence-ready infrastructure, including secure, federated data systems that enable large-scale analysis while deidentifying patient data;

''(11) facilitate the translation of research findings into clinical applications, including mechanisms for public and private funding to support Biobank Program activities; and

''(12) carry out all other activities as determined by the advisory board for the Biobank.

''(e) ADVISORY BOARD.—The Director of NIH shall establish a national advisory board to oversee the functions of the Biobank. The advisory board shall include representatives from—

''(1) the Institutes and Centers of the National Institutes of Health;

''(2) other relevant Federal agencies;

''(3) public and private research institutions, including entities that performed key participant and community engagement, genomic sequencing, and data security functions of the All of Us Research Program;

''(4) health care systems;

''(5) artificial intelligence and data experts;

''(6) clinical trial design experts;

''(7) pharmaceutical, biologic, and medical technology companies; and

''(8) experts in the ethical, legal, and social implications of science and technology.

''(f) MULTI-MODAL DATA.—The data described in subsection (c)(7) may link biological, clinical, environmental, and other data, including information related to

environmental exposures and factors identified using a life course approach.

''(g) PRIVACY PROTECTIONS AND INFORMED CONSENT.—

''(1) IN GENERAL.—The Director of NIH shall ensure that any entity collecting data or specimens from any individual through the Biobank Program or conducting any clinical trial using such data or specimens, or in any other way using such data or specimens—

''(A) collects biospecimens and associated clinical and demographic information only from participants who have given their informed consent in accordance with Federal and State law; and

''(B) protects personal privacy to the extent required by applicable Federal and State law, at minimum.

''(2) INFORMED CONSENT.— The Director of NIH shall continue to ensure that all biospecimens and associated clinical and other demographic information are collected with the informed consent and authorization of individuals participating in the Biobank Program, or their legally authorized representative, in accordance with the law.

''(h) CONGRESSIONAL NOTIFICATION.—Not later than one year after the date of the enactment of this section, and annually thereafter, the Director of NIH shall submit to the appropriate congressional committees a notification on all activities as determined by the advisory board for the Biobank.

''(i) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there is authorized to be appropriated $500,000,000 for fiscal year 2027 and each subsequent fiscal year, to remain available until expended.''.

(b) ROADMAP.—Not later than 180 days after the date of the enactment of this Act, the Director of NIH shall submit to Congress, in consultation with relevant public and private entities on the advisory board, a roadmap for implementation and augmentation of the Biobank Program established under section 404P of the Public Health Service Act, as added by subsection (a), including scientific priorities, an infrastructure development plan, a public-private partnership financing strategy, and a budget for 5 fiscal years.