The Story of ClinicalTrials.gov: Promoting Transparency and Scientific Integrity in Research

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Objectives

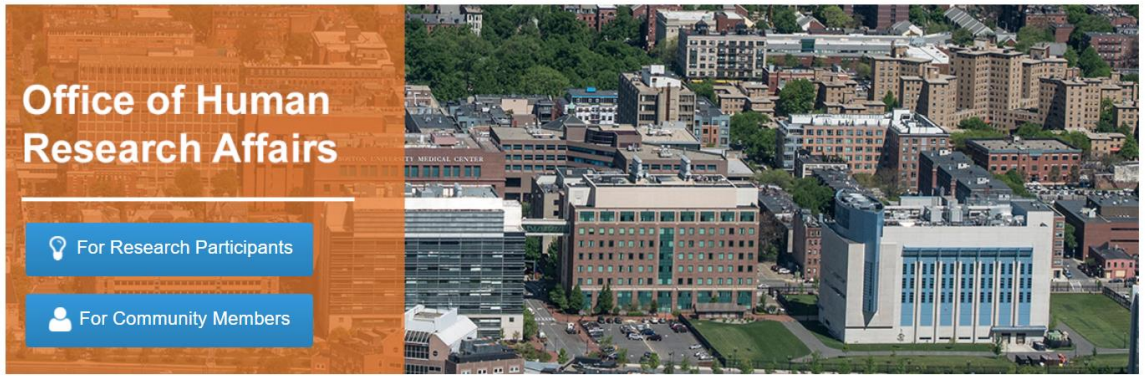
- Provide an overview and brief history of ClinicalTrials.gov and the PRS (Protocol Registration and Results System)
- Describe how ClinicalTrials.gov promotes transparency and enhances scientific integrity
  - Discuss the role of the ICMJE (International Committee Medical Journal Editors) in promoting compliance with record registration and data sharing
  - Review the requirements for posting results and required documents including the informed consent form
  - Summarize changes during the COVID-19 pandemic
  - Present the ClinicalTrials.gov modernization initiative
- Discuss enforcement of regulations and consequences of noncompliance
- Present useful ClinicalTrials.gov resources

An Overview of the History of ClinicalTrials.gov and of the PRS

(Protocol Registration and Results System)

Boston University Medical Campus and **Boston Medical Center**:
Office of Human Research Affairs

COVID-19 (Novel Coronavirus): Please click here for FAQs: Impact of COVID-19 on Human Subjects Research



Boston Medical Center and the three schools on the Boston University Medical Campus (Medicine, Public Health, and the Goldman School of Dental Medicine) are committed to performing human research in order to advance our understanding of health and disease. This research must be conducted according to the highest ethical standards and in compliance with all regulatory requirements. **The Office of Human Research Affairs (OHRA)** is responsible for the oversight of this human research to assure that we meet those ethical and regulatory expectations. OHRA accomplishes this **through its robust Human Research Protection Program (HRPP). The two main elements of the HRPP are**:

About Us
HRPP Policies
Clinical Data Warehouse
Required Training
Audits
Limited Funding Opportunities
ClinicalTrials.gov
For Research Participants
For Community Members

Quick Links

BU CTSI
CR Times Newsletter
INSPIR II
IRB Information
Look Up PI Home Institution

www.bumc.bu.edu/ohra/

COVID-19 (Novel Coronavirus): Please click here for FAQs: **Impact of COVID-19 on Human Subjects Research**

ClinicalTrials.gov

ClinicalTrials.gov Requirements

If you need any assistance (eg registering a study for the NCT#, updating existing records, posting results and/or documents, changing study contacts, verifying the record, transferring a record to another institution, etc) contact the BMC/BUMC PRS Administrator– **Karla Damus (damusk@bu.edu, 617 358 7382)**

Please use the below links for information about ClinicalTrials.gov.

What, Why, Which Studies, When

Who, How, Consent Form Posting, Legal Requirements

Guidance and Helpful Tips

About Us
HRPP Policies
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Required Training
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Limited Funding Opportunities
ClinicalTrials.gov
- What, Why, Which Studies, When
- Who, How, Consent Form Posting, Legal Requirements
- Guidance and Helpful Tips

For Research Participants
For Community Members

Quick Links

BU CTSI
CR Times Newsletter

www.bumc.bu.edu/ohra/clinicaltrials-gov/

Guidance and Helpful Tips

Guidance and Helpful Tips

For assistance, including: registration of a clinical study to obtain the NCT identifier required by the IRB for all clinical trials, accessing/becoming a ClinicalTrials.gov user, resetting a forgotten password, reporting results for registered studies, posting required documents, and scheduling a training session for PIs and research team members, investigators at BMC and BU Medical Campus should contact the PRS Administrator (Karla Damus, damusk@bu.edu, 617 358 7382).

Data sharing required by ICMJE

1. As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement.
2. Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

Data sharing statements must indicate the following: whether individual de-identified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer); what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

Data sharing resources

http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf

http://www.icmje.org/news-and-editorials/proposed-disclosure-form-editorial.pdf

http://www.icmje.org/news-and-editorials/proposed-disclosure-form.pdf

Related Websites

ClinicalTrials.gov

Register.clinicaltrials.gov

FDAAA TrialsTracker

BMJ Unreported Clinical Trial of the Week

Alltrials.net

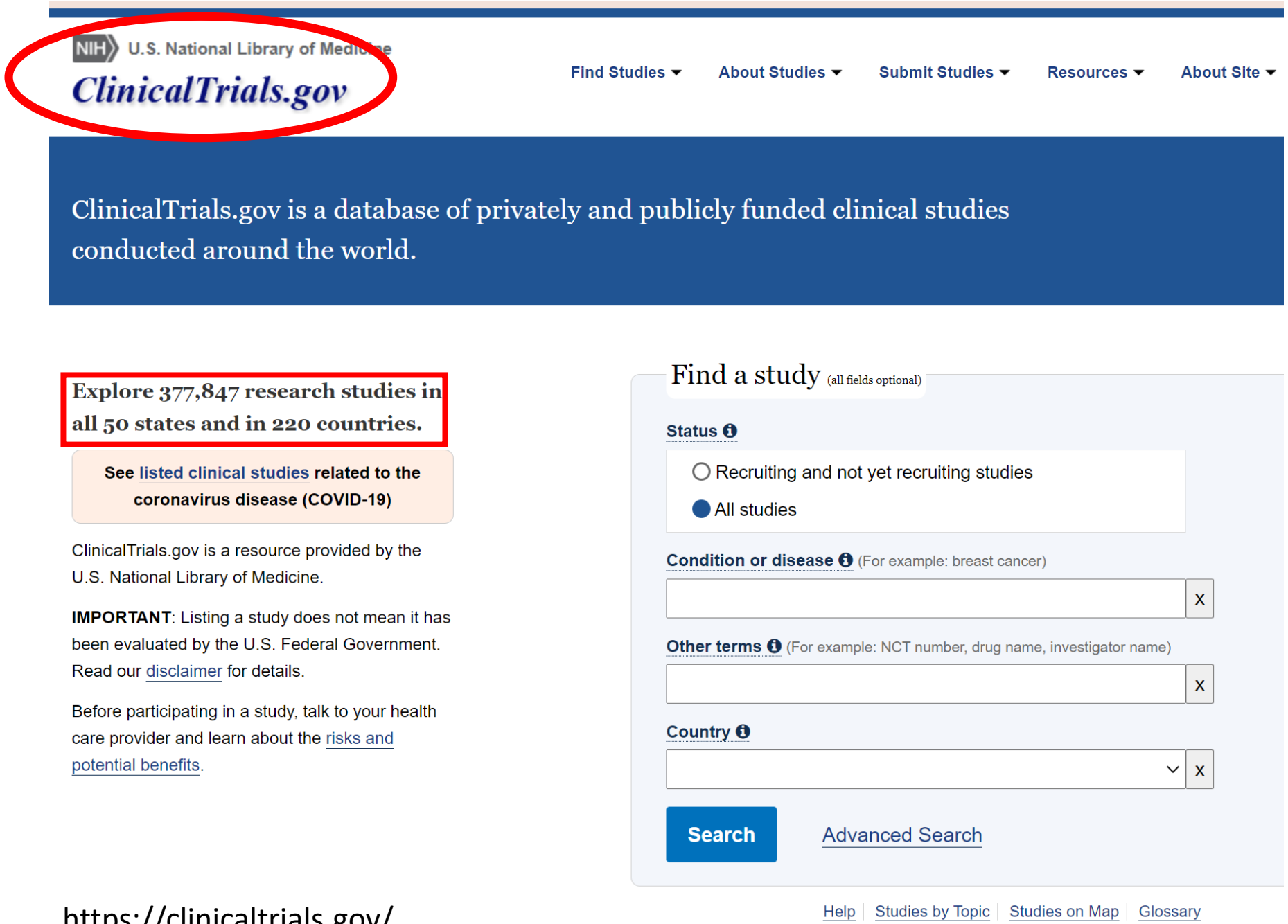
Polling Q1

1. How often have you used the public website **clinicaltrials.gov**?

    a. Never

    b. A few times

    c. Frequently



https://clinicaltrials.gov/

RESOURCES

Selected Publications
Clinical Alerts and Advisories
RSS Feeds

Trends, Charts, and Maps
Downloading Content for Analysis

Trends, Charts, and Maps

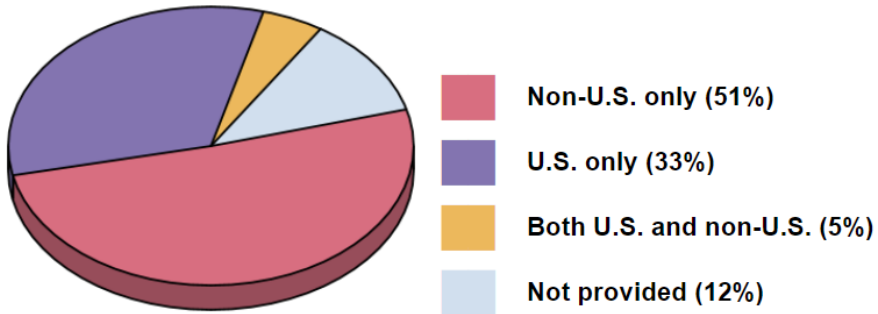
ClinicalTrials.gov currently lists 377,847 studies with locations in all 50 States and in 220 countries.

As of March 2021, ClinicalTrials.gov receives about 4.5 million visitors monthly.

Contents

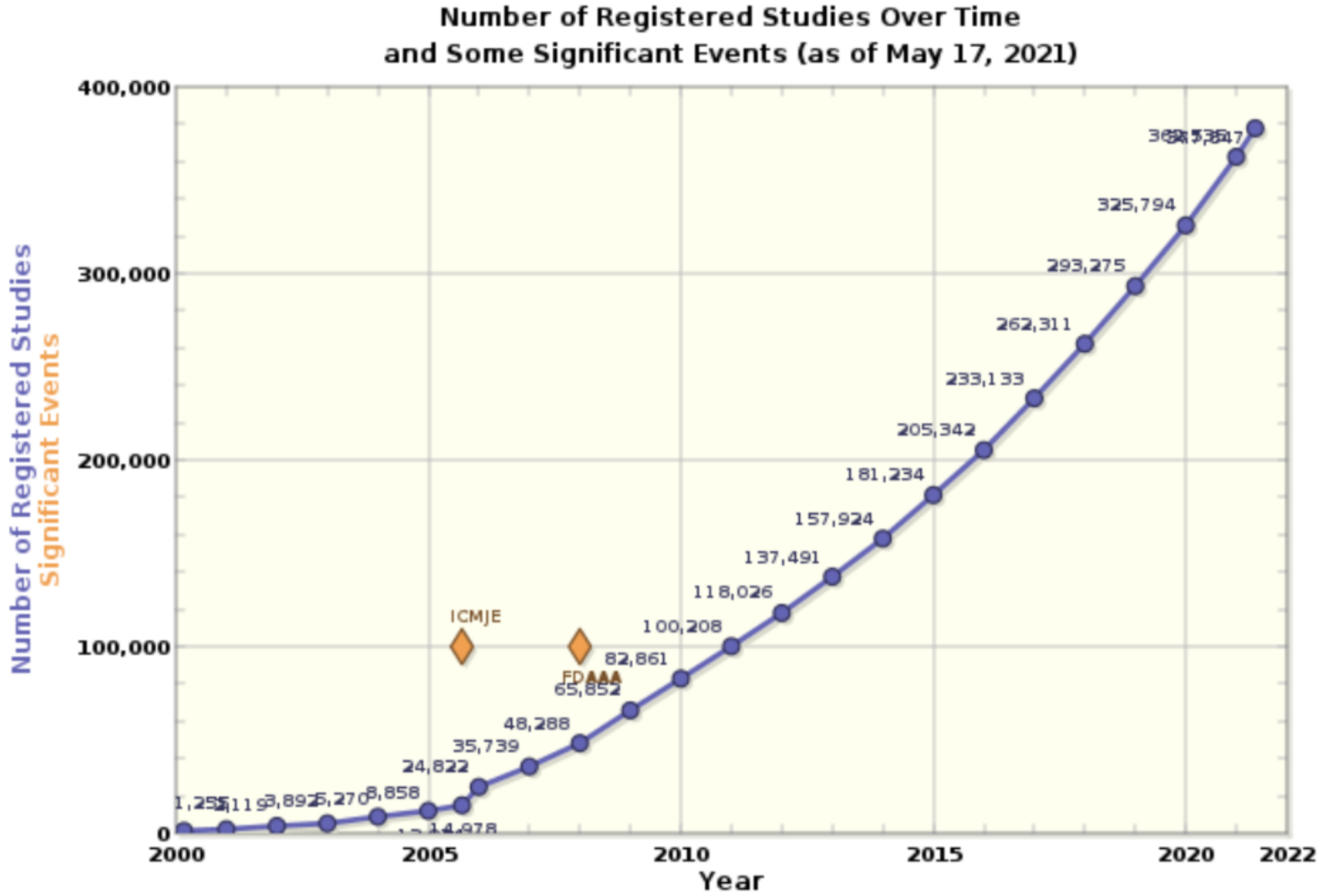
Percentage of Registered Studies by Location (as of May 17, 2021)

Total of 377,847 studies

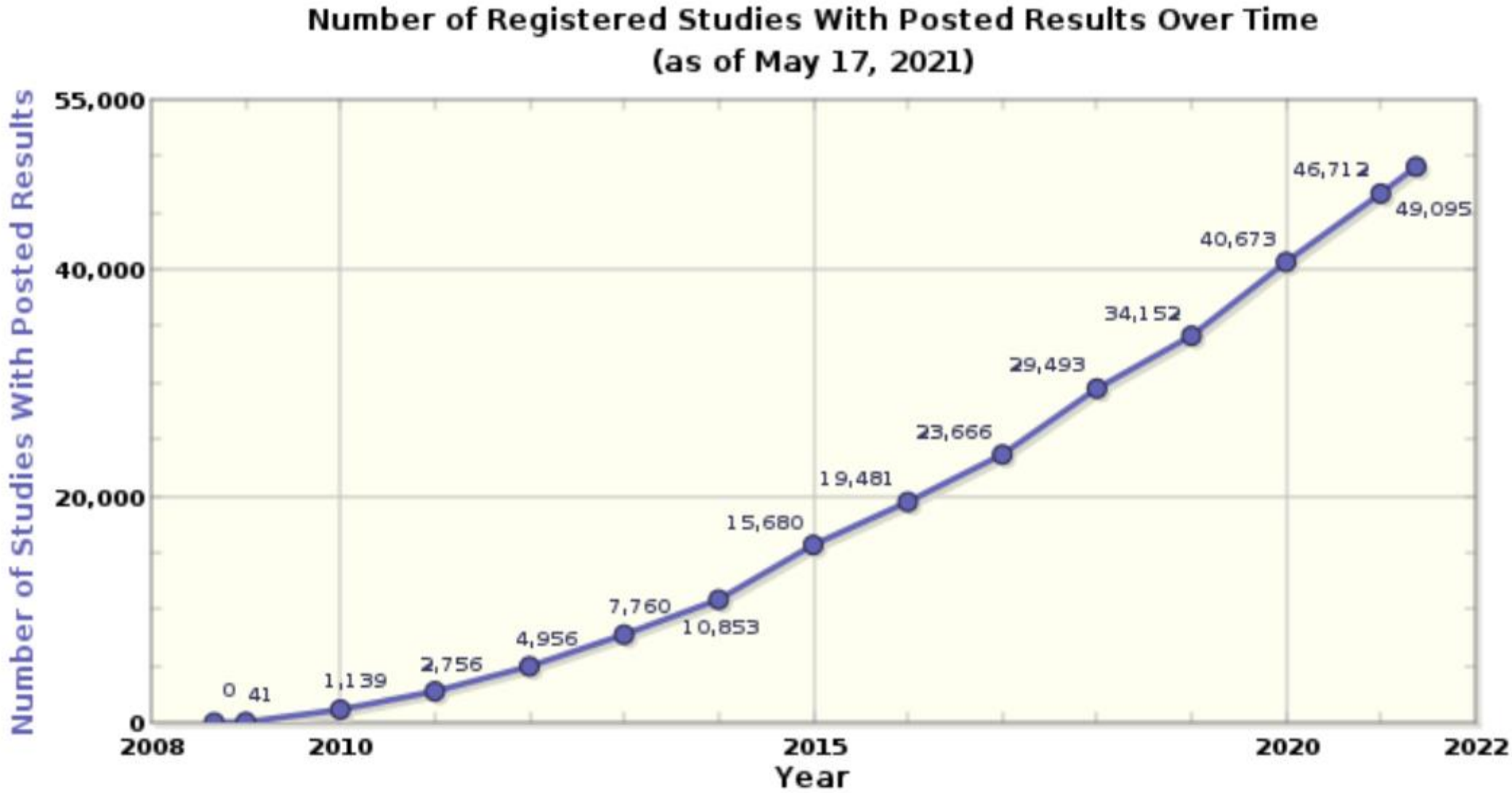


Location	Number of Registered Studies and Percentage of Total (as of May 17, 2021)
Non-U.S. only	191,842 (51%)
U.S. only	123,174 (33%)
Both U.S. and non-U.S.	19,101 (5%)
Not provided	43,730 (12%)
Total	377,847 (100%)

Study and Intervention Type (as of May 17, 2021)		Number of Registered Studies and Percentage of Total
Total		377,847
Interventional		294,317 (78%)
Type of Intervention*	**Drug or biologic**	160,146
	Behavioral, other	97,738
	Surgical procedure	30,755
	Device**	38,555
Observational		81,945 (22%)
Expanded Access		755



Source: https://ClinicalTrials.gov



Source: https://ClinicalTrials.gov

ABOUT SITE

What's New
ClinicalTrials.gov Background
About the Results Database
History, Policies, and Laws
ClinicalTrials.gov Modernization
Media/Press Resources

Linking to This Site
Terms and Conditions
Disclaimer

What's New

2021

May 17, 2021

- **Train-the-Trainer Workshop Application Period is Closed**: The application period for the Results Database Train-the-Trainer Workshop for August 2021 is closed. See the Training Materials page for more information on the workshop.

May 11, 2021

- **Downloading Content for Analysis**: The ClinicalTrials.gov Beta API introduced in July 2019 is now the operational API. The Downloading Content for Analysis page has been updated to reflect this change, including links to the current XML schema and crosswalk linking data elements to corresponding API fields. Beginning on January 1, 2022, the previous API will no longer be supported.
- **An Additional Question Addressed in the Responses to Top Questions from Responsible Parties Related to Coronavirus (COVID-19)**: An additional question (#6) and information from the NIH's Director's November 2020 Statement calling on researchers to swiftly share COVID-19 results has been added to the Responses to Top Questions from Responsible Parties Related to Coronavirus (COVID-19) (PDF). Document is available on the Support Materials page.
- **Train the Trainer**: The next Train-the-Trainer Workshop is scheduled for August 2021 and will be offered in an all-virtual format. Attendees must attend all five, two-hour live sessions on Tuesdays: August 3, August 10, August 17, August 24, and August 31. The application link is now available.

March 09, 2021

- **PRS Guided Tutorials**: The PRS Guided Tutorials have new and updated content and features in response to feedback obtained through focus groups and survey responses over the past year. Updates include improved images and zoom functionality, additional study examples from materials developed for the behavioral sciences community, and revisions to the Introduction and tutorial content for added clarity and guidance. Also, two new sections have been added: Quick Overview Guides are designed to help users get the most from the tutorials, and the PDF Library has all of the tutorial content in a single place, readily available for download. Please note that audio narration has been removed.
- **Modernization Webinar Materials Available**: A recording of the February 18 webinar and slides describing the progress of the

SUBMIT STUDIES

Submit Studies to ClinicalTrials.gov PRS
Why Should I Register and Submit Results?
FDAAA 801 and the Final Rule
How to Apply for a PRS Account
How to Register Your Study
How to Edit Your Study Record
How to Submit Your Results
Frequently Asked Questions
Support Materials
Training Materials

Related Pages

- Login to ClinicalTrials.gov PRS

Do you or someone you know want to participate in a clinical study? See information for patients and families.

Frequently Asked Questions

Contents

Polling Q2

2. Have you ever registered, updated, and/or posted results on the **PRS [register.clinicaltrials.gov]**?

    a. Yes

    b. No

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: BostonMC Admin: KarlaDamus Logout

Home > Record Summary

ID: H-33061 Reducing Socioeconomic Disparities in Health at Pediatric Visits NCT02451059

Record Summary

Home Help

Record Status

In Progress → Entry Completed → Approved → Released → PRS Review → ***Public***

Reset to In-Progress...

Record Owner:	[redacted]	Access List:	[redacted] Edit
Last Update:	05/14/2021 16:56 by KarlaDamus	Upload:	Allowed Edit
Initial Release:	05/14/2015	PRS Review:	Review History
Last Release:	05/14/2021 Receipt (PDF)	Public Site:	Last Public Release: 05/14/2021 View on ClinicalTrials.gov
		FDAAA:	Non-ACT (No FDA-regulated drug/device)

Spelling Preview Draft Receipt (PDF RTF) Download XML Admin Only: Copy Protocol Change Owner

https://register.clinicaltrials.gov/

Reducing Socioeconomic Disparities in Health at Pediatric Visits (WECARE01)

ClinicalTrials.gov Identifier: NCT02451059

Recruitment Status : Completed
First Posted : May 21, 2015
Last Update Posted : May 18, 2021

Sponsor:
Boston Medical Center

Collaborators:
Center for Community Health Education Research and Service, Inc.
National Institute on Minority Health and Health Disparities (NIMHD)

Information provided by (Responsible Party):
Boston Medical Center

Study Description

Go to

Brief Summary:
This research project is aimed to assess the effectiveness and impact of a pediatric-based intervention aimed at reducing low-income families' unmet material needs (food, housing, employment, childcare, household heat, education and learning the English language) on child health

Condition or disease	Intervention/treatment	Phase
Asthma	Behavioral: WE CARE survey	Not Applicable
Obesity	Behavioral: WE CARE Community Resource Handout	
Health Care Utilization	Behavioral: Patient Navigator	
Health Care Disparities		
Basic Unmet Social Needs		
Blood Pressure		

https://clinicaltrials.gov/ct2/show/NCT02451059

Open **Protocol Section**

Identifiers: NCT02451059 Unique Protocol ID: H-33061 Secondary IDs: 1R01MD007793-01A1

Brief Title: Reducing Socioeconomic Disparities in Health at Pediatric Visits (WECARE01)

Module Status:

- Study Identification: ✓
- Study Status: ✓
- Sponsor/Collaborators: ✓
- Oversight: ✓
- Study Description: ✓
- Conditions: ✓
- Study Design: ✓
- Arms and Interventions: ✓
- Outcome Measures: ✓
- Eligibility: ✓
- Contacts/Locations: ✓
- IPD Sharing Statement: ✓
- References:

Open **Document Section**

Documents that may be uploaded include:

- Study Protocol and Statistical Analysis Plan - only required with results information for studies with a Primary Completion Date on or after January 18, 2017
- Informed Consent Form - optional under 42 CFR Part 11, but may be required by funder, including if study is conducted or supported by a Common Rule (45 CFR 46) department or agency

Uploaded PDF/A Documents:

Results Section

Enter Results Results submission is required by FDAAA 801 for certain applicable clinical trials of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.

Delay Results For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: When Do I Need to Register and Submit Results?

Need help with Results? Contact ClinicalTrials.gov PRS to request one-on-one assistance from one of our experts.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section

ID: H-33061 Reducing Socioeconomic Disparities in Health at Pediatric Visits

Protocol Section

Record Summary Preview Edit All Help Definitions

Edit

Study Identification

Unique Protocol ID: H-33061
Brief Title: Reducing Socioeconomic Disparities in Health at Pediatric Visits (WECARE01)
Official Title: Reducing Socioeconomic Disparities in Health at Pediatric Visits
Secondary IDs: 1R01MD007793-01A1 [U.S. NIH Grant/Contract Award Number]

Edit

Study Status

Record Verification: May 2021
Overall Status: Completed
Study Start: September 2015 [Actual]
Primary Completion: December 29, 2020 [Actual]
Study Completion: December 29, 2020 [Actual]

Edit

Sponsor/Collaborators

Sponsor: Boston Medical Center
Responsible Party: Sponsor
Collaborators: Center for Community Health Education Research and Service, Inc.
National Institute on Minority Health and Health Disparities (NIMHD)

Edit

Oversight

U.S. FDA-regulated Drug: No
U.S. FDA-regulated Device: No
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Approved Approval Number: H-33061
Board Name: Boston University Medical Campus Institutional Review Board
Board Affiliation: Boston Medical Center
Phone: 617-638-7207 Email: medirb@bu.edu
Address:
560 Harrison Ave
3rd Floor, Suite 300
Boston, MA 02118
Data Monitoring: No
FDA Regulated Intervention: No

Open

Contacts/Locations

Central Contact Person: Arvin Garg, MD MPH
Telephone: (617) 414-3817
Email: Arvin.Garg@bmc.org
Central Contact Backup: Annelise C Brochier, MPH
Telephone: (617) 414-5974
Email: annelise.brochier@bmc.org
Study Officials: Arvin Garg, MD MPH
Study Principal Investigator
Boston University Medical Campus

▼Locations:

United States, Massachusetts

Greater Roslindale Medical and Dental Center
Roslindale, Massachusetts, United States, 02131
Contact: Jennifer Lo, MD 617-323-4440 jennifer.lo@bmc.org
Uphams Corner Health Center
Dorchester, Massachusetts, United States, 02125
Contact: Edward Levy, MD 617-287-8000 ELevy@uphams.org
Codman Square Health Center
Boston, Massachusetts, United States, 02124
Contact: Stephen Tringale, MD 617-825-9660 Stephen.Tringale@codman.org
South End Community Health Center
Boston, Massachusetts, United States, 02118
Contact: Robyn Riseberg, MD 617-425-2000 robyn.riseberg@bmc.org
Mattapan Community Health Center
Mattapan, Massachusetts, United States, 02126
Contact: Ramon Cancino, MD 617-296-0061 Cancinor@matchc.org
Dorchester House Multi-Service Center
Boston, Massachusetts, United States, 02122
Contact: Holly Goodale, MD 617-288-3230 Holly.Goodale@dorchesterhouse.org

Edit

IPD Sharing Statement

Plan to Share IPD: No

Edit

References

▼Citations:

Links:

Available IPD/Information:

Selected events, policies, and laws related to the development and expansion of ClinicalTrials.gov

- 1997: Congress Passes Law (FDAMA) Requiring Trial Registration
- 2000: NIH Releases ClinicalTrials.gov Web Site
- 2000–2004: FDA Issues Guidance for Industry Documents
- 2004: ClinicalTrials.gov Wins the Innovations in American Government Award
- 2005: International Committee of Medical Journal Editors Requires Trial Registration
- 2005: State of Maine Passes Clinical Studies Registration Law (Repealed in 2011)
- 2006: World Health Organization Establishes Trial Registration Policy
- 2007: Congress Passes Law (FDAAA) Expanding ClinicalTrials.gov Submission Requirements
- 2008: ClinicalTrials.gov Releases Results Database
- 2008: Declaration of Helsinki Revision Promotes Trial Registration and Results Dissemination
- 2009: Public Meeting Held at the National Institutes of Health
- 2013: European Medicines Agency Expands Clinical Trial Database to Include Summary Results
- 2014: Notice of Proposed Rulemaking (NPRM) for FDAAA 801 Issued for Public Comment
- 2014: NIH Draft Policy on Registration and Results Submission of NIH-Funded Clinical Trials Issued for Public Comment
- 2015: National Cancer Institute Issues Clinical Trial Access Policy
- 2016: Final Rule for FDAAA 801 Issued
- 2016: Final NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information Issued
- 2017: Revised Common Rule (45 CFR 46) Issued
- 2020: Federal Court Decision in *Seife et al. v. HHS et al.*, 18-cv-11462 (NRB) (S.D.N.Y. Feb. 24, 2020)

1997: Congress Passes Law (FDAMA) Requiring Trial Registration

- The first U.S. Federal law to require trial registration was the Food and Drug Administration Modernization Act of 1997 (FDAMA)
- Section 113 of FDAMA (FDAMA 113) required the NIH to create a public information resource on certain clinical trials regulated by FDA
  - It required that the registry include information about federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions.
- The information in the registry was intended for a wide audience, including individuals with serious or life-threatening diseases or conditions, members of the public, health care providers, and researchers.

2000: NIH Releases ClinicalTrials.gov Web Site

- With input from FDA and others, the NIH National Library of Medicine (NLM) developed ClinicalTrials.gov.
  - The first version of ClinicalTrials.gov was made available to the public on February 29, 2000.
  - At the time, ClinicalTrials.gov primarily included NIH-funded studies.
- NLM Press Release: National Institutes of Health Launches ClinicalTrials.gov (February 29, 2000)

2005: International Committee of Medical Journal Editors Requires Trial Registration

- In 2005 the International Committee of Medical Journal Editors (ICMJE) began *requiring trial registration as a condition of publication.*
  - Trials that began before July 1, 2005:
    - Investigators should register trials that began enrolling patients any time before July 1, 2005 as soon as possible if they wish to submit them to a journal that follows the ICMJE policy. However, beginning on September 13, 2005, ICMJE journals will consider such trials only if they were adequately registered before journal submission. The ICMJE journals will accept "retrospective registration" of trials that began before July 1, 2005 (retrospective meaning registration occurs after patient enrollment begins).
  - Trials that began after July 1, 2005:
    - ICMJE journals will consider trials beginning on or after July 1, 2005 **only if registration occurred before the first patient was enrolled ("prospective registration")**

- ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Obligation to Register Clinical Trials
- ICMJE: Frequently Asked Questions About Clinical Trials Registration

2007: Congress Passes Law (FDAAA) Expanding ClinicalTrials.gov Submission Requirements

- In 2007 the requirements for submission to ClinicalTrials.gov were expanded after Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA)
- Section 801 of FDAAA (FDAAA 801) required more types of trials to be registered; additional trial registration information; and the submission of summary results, including adverse events, for certain trials.
  - The law also included penalties for noncompliance, such as the withholding of NIH grant funding and civil monetary penalties of up to $10,000 a day.

- FDAAA 801 and the Final Rule
- NIH Office of Extramural Research: Frequently Asked Questions: FDAAA - Further Resources for NIH Grantees

2008: ClinicalTrials.gov Releases Results Database

- In September 2008, as required by FDAAA 801, ClinicalTrials.gov began allowing sponsors and principal investigators to submit the results of clinical studies
- The submission of adverse event information was optional when the results database was released but was required beginning in September 2009

- NLM Technical Bulletin: ClinicalTrials.gov to Include Basic Results Data

2008: Declaration of Helsinki Revision Promotes Trial Registration and Results Dissemination

- In October 2008 the 59th World Medical Association (WMA) General Assembly amended the Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.
  - Two newly added principles (paragraphs 19 and 30) considered the prospective registration and the public disclosure of study results to be ethical obligations.
- In October 2013 the 64th WMA General Assembly modified these two principles. In particular, paragraph 35 (formerly 19) required prospective registration, as follows: "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject."
  - Paragraph 36 (formerly 30) promotes the public disclosure of study results as an ethical obligation and states, in part, "Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties [i.e., researchers, authors, sponsors, editors, and publishers] should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available.“

- WMA 2013 Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

2016: Final Rule for FDAAA 801 Issue

- In September 2016, the U.S. Department of Health and Human Services issued a Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) that *clarifies and expands the regulatory requirements and procedures for submitting registration and summary results information of clinical trials on ClinicalTrials.gov, in accordance with* FDAAA 801.
- The final rule is intended to make it clear to sponsors, investigators, and the public which trials must be submitted, when they must be submitted, and whether compliance has been achieved.
  - For example, the final rule clarifies the definition of an **Applicable Clinical Trial (ACT)** and provides structured criteria for determining which studies are considered to meet the definition.
- The final rule also expands the FDAAA 801 requirements by requiring the submission of results information for trials of unapproved products.
  - The regulation became effective on **January 18, 2017** and responsible parties are expected to be in compliance as of **April 18, 2017**.

2016: Final NIH Policy on the Dissemination of NIH-funded Clinical Trial Information Issued

- In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov.
- Under this policy, **every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.**
- This policy is effective for *intramural and extramural* applications for funding, including grants, other transactions, and contracts **submitted on or after January 18, 2017**.

2017: Revised Common Rule (45 CFR 46) Issued

- In January 2017, nearly 20 Federal department and agencies issued a revised Federal Policy for the Protection of Human Subjects (also known as subpart A of 45 CFR part 46, or the "Common Rule").
  - The revisions were designed to modernize, strengthen, and make more effective the Common Rule originally promulgated in 1991.
  - The revised Common Rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. It became effective on July 19, 2018, as amended.
- The revised Common Rule (45 CFR 46.116(h)) requires that *for any clinical trial conducted or supported by a Common Rule department or agency, one consent form used in enrolling participants be posted on a publicly available Federal website within a specific time frame*.
  - In an August 2018 announcement, ClinicalTrials.gov and Regulations.gov were identified as the publicly available federal websites that will satisfy the consent form posting requirement.

2020: Federal Court Decision in *Seife et al. v. HHS et al.*, 18-cv-11462 (NRB) (S.D.N.Y. Feb. 24, 2020)

- On February 24, 2020, a Federal court held that Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) requires submission of results information for an "applicable clinical trial" ("ACT") that was initiated after September 27, 2007, or that was ongoing as of December 26, 2007, if the ACT studies a product that is approved, licensed, or cleared by the Food and Drug Administration (FDA) at any time, including after the ACT's primary completion date.
- On September 21, 2016, the Department of Health and Human Services ("HHS") published the Final Rule for Clinical Trials Registration and Results Information Submission (81 FR 64981). The preamble to the Final Rule states that a responsible party *is not required to submit to the ClinicalTrials.gov results* information under sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service (PHS) Act *for an ACT that was completed before January 18, 2017*, the effective date of the Final Rule, if the ACT studied a product that was not approved, licensed, or cleared for any use until after the ACT's primary completion date (81 FR 65067).
- On February 24, 2020, a Federal court rejected this interpretation, holding that FDAAA 801 requires responsible parties to submit to the ClinicalTrials.gov results information required under section 402(j)(3)(C) of the PHS Act, which includes information required under section 402(j)(3)(I) of the PHS Act, for ACTs subject to the registration requirements and *with a primary completion date before January 18, 2017, if the ACT studies a product that is approved, licensed, or cleared after the ACT's primary completion date*.

Polling Q3

3. Since clinicaltrials.gov was created by the NLM in 2000, what has had the largest impact on **increasing registration** of clinical studies on that website?

a. ICMJE trials registration policy of 2005

b. FDAAA [FDA Amendment Act] of 2007

c. Final NIH Policy on the Dissemination of NIH-funded CT Information of 2016

d. Final Rule for FDAAA 801 of 2016

How Clinical Trials.gov Promotes Transparency and Scientific Integrity

Transparency promotes access to the evidence or data used to support empirical research claims and assesses how they relate to broader claims, and evaluate whether they have been interpreted or analyzed correctly.

Scientific integrity deals with best practices or rules of professional practice of researchers. It stems from an OECD (Organization for Economic Co-operation and Development) report of 2007, and is set in the context of the replication crisis and the fight against scientific misconduct.

> *Replication crisis* is the finding that many scientific studies are difficult or impossible to replicate or reproduce. It most severely affects the social sciences and medicine
> *Scientific misconduct* is the violation of the standard codes of scholarly conduct and ethical behavior in the publication of professional scientific research.

Elements of Clinical Trial Transparency

Public disclosure of:

- Protocol summaries synopsis
- Clinical results or summary tables
- Full protocol and statistical analysis plan (SAP)
- Complete Clinical Study Report (CSR)
- Pending requirements
  - anonymized patient data
  - plain (lay) language results summaries

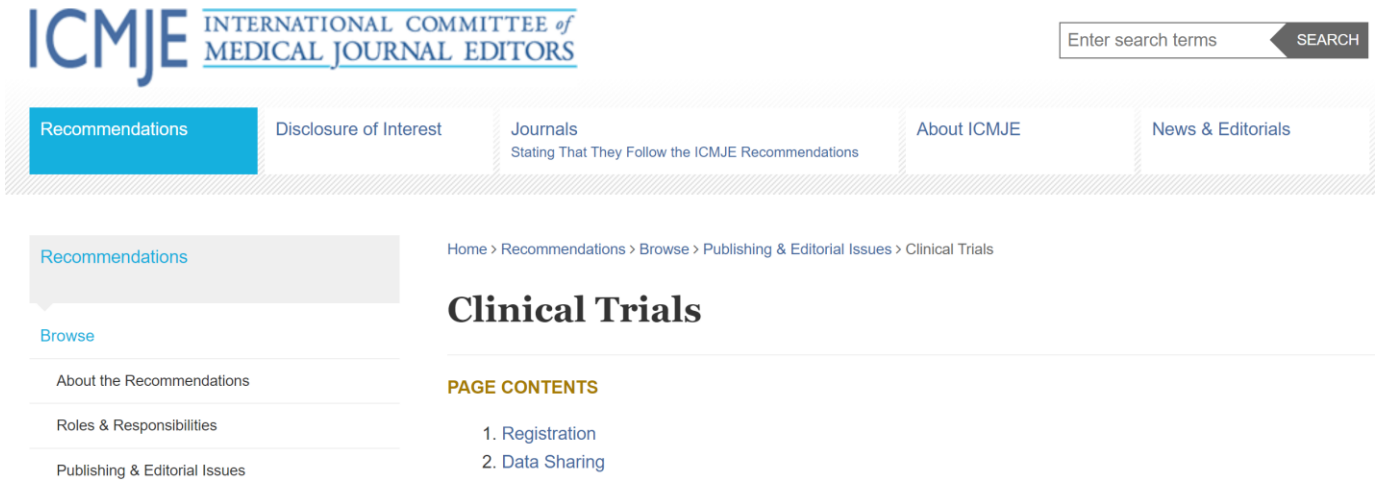
Benefits of Comprehensive Registration and Results Reporting

- They contribute to increased public trust in clinical research
- Honor commitment to participants that their contributions will advance science
- Support enrollment
- Mitigate positive results publication bias
- Advance stewardship and accountability
- Identify unmet research needs
- Facilitate complete reporting
- Avoid unnecessary study duplication
- Evaluate research integrity
- Support evidence-based medicine

Which clinical studies should be registered and when on ClinicalTrials.gov?

- BMC/BU Medical Campus HRPP policies require that **all studies meeting the definition of a clinical trial according to the International Committee of Medical Journal Editors (ICJME)** must be registered with ClinicalTrials.gov **before final IRB approval is issued** (note that IRB submission and review can proceed while the NCT# is being obtained).
  - ***ICMJE definition of a clinical trial***: Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome.
    - Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.
    - Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.
- ***NIH definition of a clinical trial***: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
  - The HHS Final Rule and the NIH Policy describe which studies must be registered and post results on ClinicalTrials.gov. Summary of HHS Final Rule and NIH Policy on Registration/Reporting in ClinicalTrials.gov in NEJM (Nov. 2016)

The role of the ICMJE in promoting compliance with record registration



- The purpose of clinical trial registration is to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing into which they might want to enroll, and to help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering.
- Retrospective registration, for example at the time of manuscript submission, meets none of these purposes. Those purposes apply also to research with alternative designs, for example observational studies.
    - For that reason, the ICMJE encourages registration of research with non-trial designs, but because the exposure or intervention in non-trial research is not dictated by the researchers, the ICMJE does not require it.

The role of the ICMJE in promoting data sharing

Data sharing required by ICMJE

- As of July 1, 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement.
- Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration.
  - If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.
- Data sharing statements must indicate the following:
  - whether individual de-identified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer);
  - what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.);
  - when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

Which clinical studies must post results and documents on ClinicalTrials.gov and when?

- All NIH funded clinical trials (even pilot and phase 1 trials) submitted on or after January 18, 2017
- All Applicable Clinical Trials (ACTs), certain clinical trials subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801)
- All studies where the award letter stipulates that results must be posted on ClinicalTrials.gov

When should results be posted?

- ***Results should be posted within 10 months of the actual primary completion date***
  - CTgov regulations require the results should be posted within 12 months of the PCD
  - There are rare exceptions which allow a possible delay in posting results up to 2 years

***P*osting results on CTgov is NOT considered to be prior publication.**

- http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html (paragraph 3 in Section 1)

Applicable Clinical Trial (ACT)

- Interventional studies of drugs, biologics and devices if the trial is subject to the registration and results reporting requirements in the FDAAA.
- A drug ACT is a controlled clinical investigation, other than a Phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.
- A device ACT is either:
  - a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects
    - other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes
  - a pediatric post-market surveillance of a device as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) Under 42 CFR 11.22(b) for Clinical Trials Initiated on or After January 18, 2017[1]

Instructions: Answer the following questions to evaluate whether the study is an applicable clinical trial (ACT). Use the accompanying "Elaboration" for additional information to help answer the questions.

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)?	☐	☐
a. Is at least one study facility located in the United States or a U.S. territory? *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.		
b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes."		
c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? *Product Manufactured in and Exported from the U.S.* data element is "Yes."		
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

Which clinical studies must post an IRB approved consent form and when on ClinicalTrials.gov?

- One of the revisions of the 2018 Common Rule that became effective on January 21, 2019 [45 CFR 46.116(h)] specifies that a consent form must be posted on a federal website for all clinical trials who receive specific federal funding* and are either
  - (a) approved by an IRB on or after January 21, 2019 or
  - (b) approved earlier but transitioned to Revised Common Rule requirements earlier than 61 days after the last study visit.
- The requirement states that:
  - an unsigned copy of **one** IRB-approved consent form that has been used in enrolling participants in a clinical trial conducted or supported by a Common Rule department/agency
  - must be posted on a publicly available federal website
    - ClinicalTrials.gov [required by BMC/BUMC HRPP policy]
    - Regulations.gov (in a docket folder, Docket ID: HHS-OPHS-2018-0021)
  - after recruitment closes and no later than 60 days after the last study visit
- Compliance is required for all studies that meet the Common Rule definition of a clinical trial-
  - *"a research study in which one or more human subjects are prospectively assigned to one or more interventions … to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes"*. This includes social, behavioral and educational clinical trials.
- The purpose of the consent form-posting requirement is to be more transparent about consent forms being used in clinical trials and to ultimately improve the quality of consent forms.

Changes during the COVID-19 pandemic

COVID-19 Information

Public health information (CDC) | Research information (NIH) | SARS-CoV-2 data (NCBI) | Prevention and treatment information (HHS) | Español

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site | PRS Login

Home > Search Results

Modify Search | Start Over

5706 Studies found for: **COVID-19**

Also searched for **COVID** and **SARS-CoV-2**. See Search Details

Your search included: **COVID-19**

Learn more about clinical studies related to COVID-19:

- **ClinicalTrials.gov**: Federally-funded clinical studies related to COVID-19
- **WHO Trial Registry Network**: COVID-19 studies from the ICTRP database
- **NIH**: COVID-19 Treatment Guidelines
- **ClinicalTrials.gov**: Views of Listed COVID-19 Studies (Beta)

List | By Topic | On Map | Search Details

Hide Filters

Download

Filters

Apply | Clear

Status

Recruitment :

Showing: 1-100 of **5,706** studies 100 studies per page

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Recruiting	Duvelisib to Combat **COVID-19**	• **COVID-19**	• Drug: Duvelisib • Procedure: Peripheral blood draw • Drug: Placebo	• Missouri Baptist Medical Center Saint Louis, Missouri, United States • Washington University School of Medicine Saint Louis, Missouri, United States

NIH Director's Statement " November 10, 2020

NIH calls on clinical researchers to swiftly share COVID-19 results

NIH is taking an all-hands-on-deck approach to speeding life-saving research for vaccines, treatments, and diagnostic tests to end the COVID-19 pandemic. Through the establishment of major public-private initiatives such as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) and the Rapid Acceleration of Diagostics (RADx) initiatives, NIH and its partners have launched dozens of COVID-19 vaccine and treatment clinical trials and funded dozens of new and innovative testing technologies at an unprecedented rate.

To maintain this record pace, it will be crucial for clinical researchers involved in COVID-19 and SARS-CoV-2 clinical trials to share their results as swiftly as possible. Toward this end, I strongly encourage the clinical research community to register their clinical trials and submit summary results information for COVID-19 and SARS-CoV-2 trials as quickly as possible and ahead of regulatory and policy deadline requirements to ClinicalTrials.gov, the publicly accessible database operated by NIH's National Library of Medicine.

To ensure such information is accessible as quickly as possible, NIH is prioritizing the processing of COVID-19 submissions to ClinicalTrials.gov to make the information rapidly available in a matter of days, not weeks. We are also providing one-on-one support to researchers during the process of submitting results information to ClinicalTrials.gov to address questions and optimize reporting.

"I strongly encourage the clinical research community to register their clinical trials and submit summary results information for COVID-19 and SARS-CoV-2 trials as quickly as possible and ahead of regulatory and policy deadline requirements to ClinicalTrials.gov, …"

Francis S. Collins, MD, PhD

COVID-19 (Novel Coronavirus): Please click here for FAQs: Impact of COVID-19 on Human Subjects Research

FAQs: Impact of COVID-19 on Human Subjects Research

Last updated April 14, 2021.

Click here for a pdf version of these FAQs. For information on the process to restart in-person human subjects research at BMC and BU Medical Campus, please see FAQ #30 below.

Please also see:
– Information from the CTSI: http://www.bu.edu/ctsi/covid-action/
– Information from BU: https://www.bu.edu/covid-19-information/
– Information from BMC: https://www.bmc.org/covid-19/covid-19-research-related-information
– Information on COVID-19-Releated Research Workflow and Review Processes from BMC Research

27. What updates are required to ClinicalTrials.gov records? (NEW 3/25/20)

Certain studies listed on ClinicalTrials.gov that have paused recruitment should have their recruitment status changed from Recruiting or Enrolling by Invitation to Suspended, within 30 days of the change. The ClinicalTrials.gov administrator, Karla Damus (damusk@bu.edu) is in the process of contacting study teams where this change may be required and will offer assistance, or will make the status change, as requested by the study team. In addition, it is likely that the Primary Completion Date and the Study Completion Date will have to be extended for paused studies. Again, Karla will be contacting and assisting study teams as their Primary Completion Date or Study Completion Date approaches. Please contact Karla with questions or for additional information.

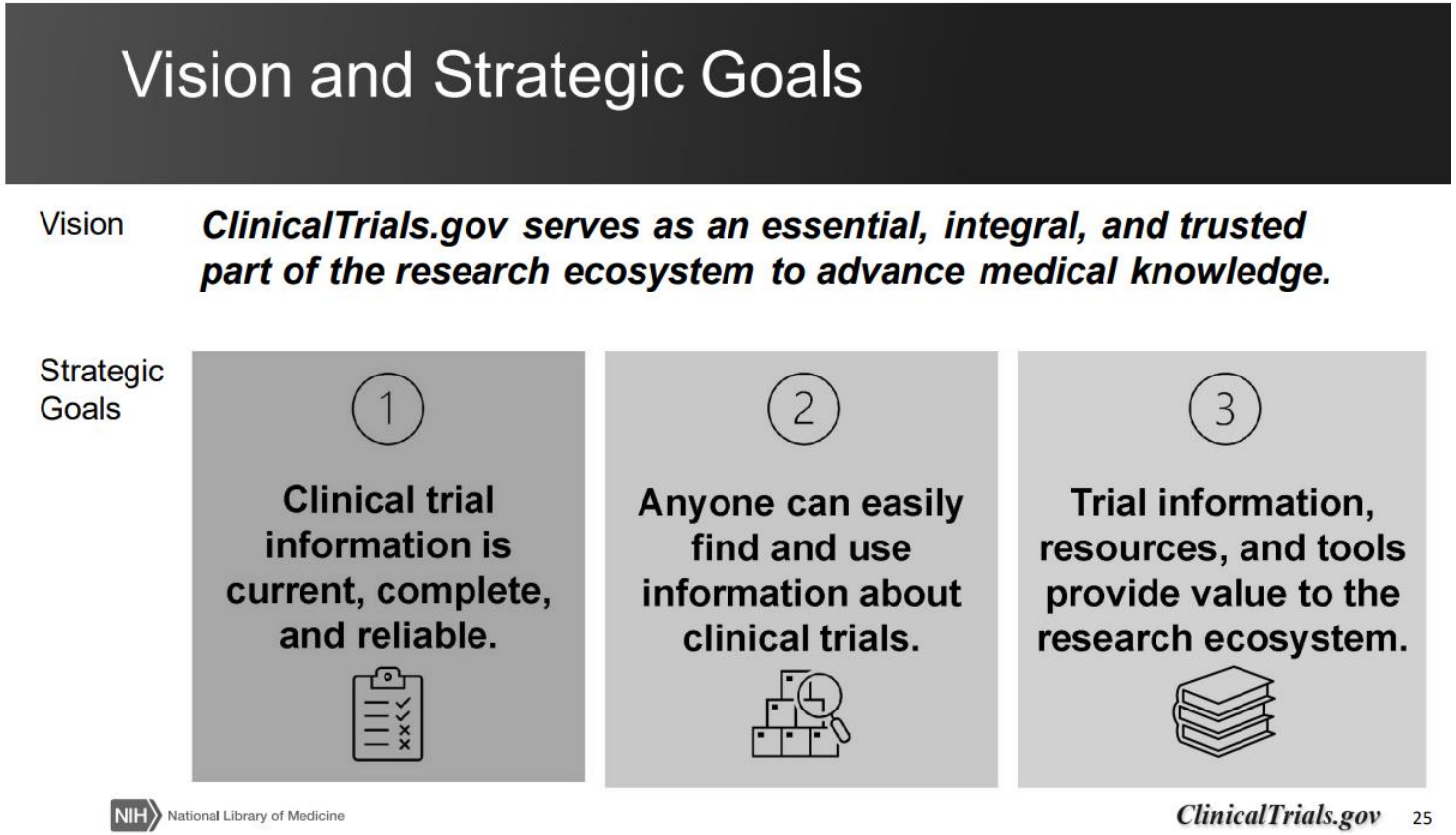
www.bumc.bu.edu/irb/faqs-impact-of-covid-19-on-human-subjects-research/

Implementation of the BUMC/BMC Covid-19 CTgov Policy

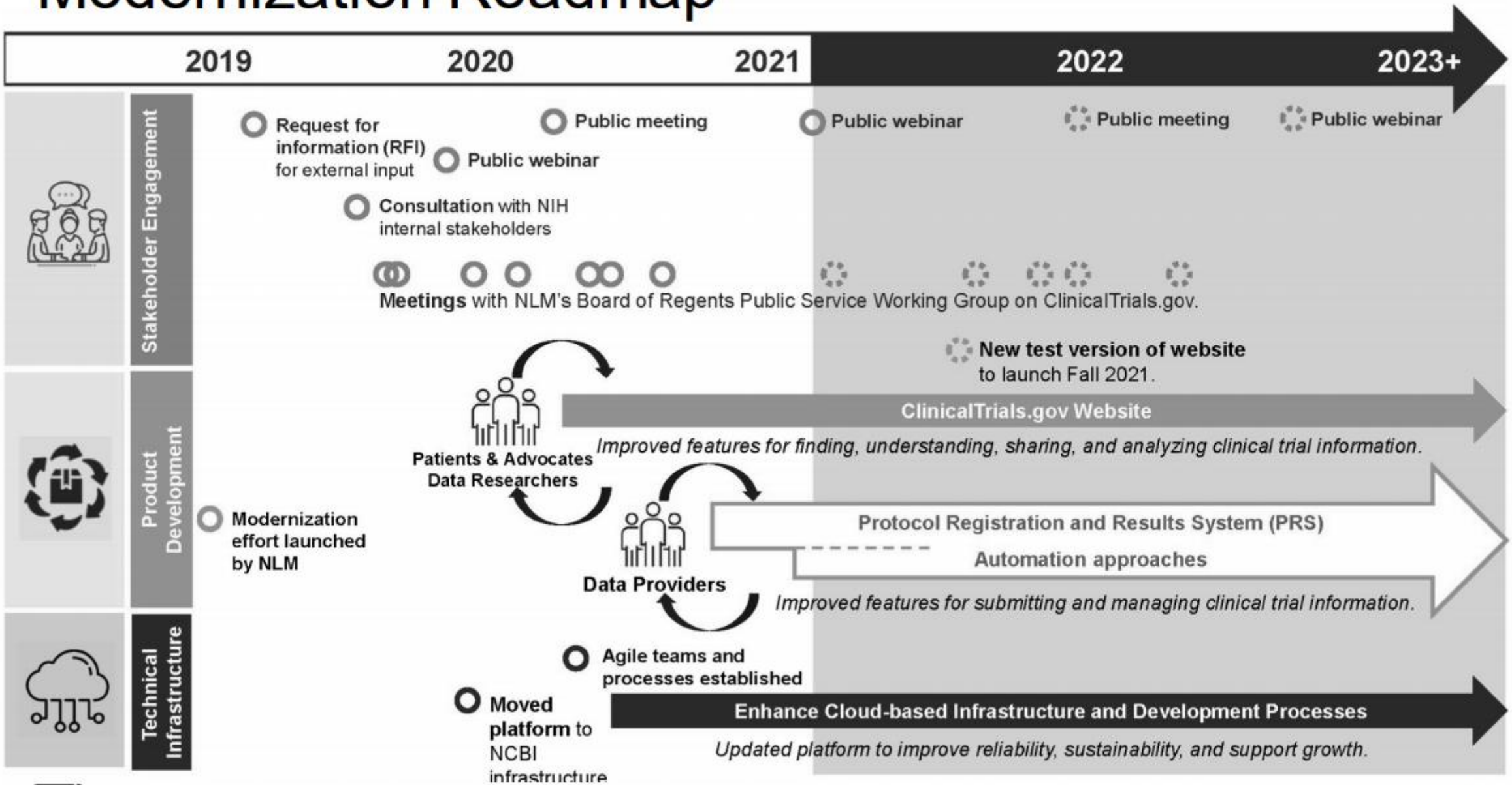
- The PRS Administrator contacted each study on CTgov identified from the ***Planning Report*** as either '**Enrolling by Invitation**' or '**Recruiting**' by a personalized email about the policy and offering assistance to edit their record/s and respond to questions/concerns.
  - This was a very time consuming process which often led to multiple emails and/or a phone discussion/s
  - Any primary completion and study completion dates 'anticipated' by July 2020 were discussed with the research team and if needed, edited forward so as not to become in arrears during the research pause
  - The emails also reminded the research team to go back into the record and edit the study status from 'Suspended' to the appropriate category in a timely fashion [within 30 days] once research resumes
    - The PRS administrator will monitor the suspended studies to insure that this occurs with emails and phone calls as warranted
  - The tracking system for compliance with Common Rule ICF posting was also reviewed and discussed with the team, editing the window as needed

ClinicalTrials.gov Modernization Initiative

- Goal- Ensure ClinicalTrials.gov continues to be a trusted and valued premier public health resource that provides maximum value to the public and serves its mission well into the future.



Modernization Roadmap



Key RFI Response Themes

Public Site (ClinicalTrials.gov)

- Search Options and Managing Search Results
  - Make search more user friendly
  - Add more options to search
  - Improve tools for managing search results
- Study Record Format and Content
  - Standardize more content
  - More prominently display certain content; make more content available
  - Add features to make using content easier
- Plain Language Information
  - General health information and learning about study participation
  - Resources for using site features
  - Study record content

PRS (register.ClinicalTrials.gov)

- Data Structure and Format
  - Additional standardization for some data elements
  - More flexibility for data elements and record structure
  - Structural support for a variety of study designs
- Data Entry, Submission, and Quality Control (QC) Review
  - More tools to simplify data entry
  - Additional streamlining of QC review process
- Workflow Management
  - More customizable features to manage workload

Summary

- Aim to deliver an improved user experience to further advance the goals of comprehensive registration and results reporting.
- RFI feedback combined with user feedback loops are driving the modernization effort; coordinated with infrastructure upgrades.
- Approach will allow adequate time for users to try test versions of new systems and allow for improvements before implementation.
  - ClinicalTrials.gov website – test version planned for Fall 2021
  - Protocol Registration and Results System (PRS) – in early stages of planning and development
- We will continue to keep stakeholders well-informed.

Enforcement of Regulations and Consequences of Noncompliance

Who is responsible for compliance with registration, updating, results reporting, and document posting on ClinicalTrials.gov?

- Compliance with regulations that pertain to ClnicalTrials.gov is the responsibility of either the Principal Investigator (for PI initiated studies) or the sponsor.
  - This begins with complying with all BMC/BU Medical Campus HRPP Policies that pertain to clinical trials (section 6.6.9).
  - The BMC/BU Medical Campus Administrator of ClinicalTrials.gov provides information, guidance and support in all aspects of ClnicalTrials.gov with additional oversight by the BMC Research Compliance Officer and the Director of the Office of Human Research Affairs (OHRA).
- For investigator-initiated clinical trials, the PI is considered the Responsible Party (RP), and is the one who has to complete the registration. For multi-center clinical trials, someone other than the local PI usually fulfills this responsibility (eg the sponsor).
- The RP must maintain and verify the information about the trial, including the overall study status, keeping all 'anticipated' study dates current, integrating relevant IRB amendments and recruitment information, and posting final results and documents, if required.
  - Different types of information require updating within 15 or 30 days after a change and at a minimum the entire record needs to be reviewed and all information checked for accuracy/verified at least annually.
- The PI/RP can identify members of their research team who can also have access to the record and thereby assist in maintaining and making needed edits to the record.
  - Their names should be given to the PRS Administrator who can make them new users and give them access to their specific study/ies.
  - However, only the RP or sponsor can release the record for ClinicalTrials.gov PRS review, and until the record is released and then reviewed the changes/edits cannot be published/made public on ClinicalTrials.gov.

Consequences for Noncompliance

- Unable to have manuscripts published in journals that subscribe to ICMJE policies if the trial was not registered on CTgov prior to enrollment of any participant
  - BMC/BUMC HRPP policies state that the trial must be registered before IRB approval
  - CTgov regulations state that the trial must be registered within 21 days of enrollment
- Potential legal consequences for responsible parties and their institution if they do not comply with the requirements to submit registration and results information on ACTs, described in 42 CFR 11.66
  - Potential legal consequences include civil or criminal judicial actions, civil monetary penalty actions, and grant funding actions.
  - In 2019, fines for late FDAAA are $12,103/day
- For NIH funded studies, grant funds can be withheld for a specific study or for the institution
- The institution/organization can be featured in the weekly BMJ article on CTgov noncompliance

Introducing unreported clinical trial of the week

March 29, 2018

Every week this new series will uncover an unreported clinical trial

Ben Goldacre, Nicholas DeVito, Carl Heneghan, Síle Lane, Richard Stephens

Clinical trials are the gold standard in medicine. But trial results are still routinely left unreported. [1,2] This problem has been well documented since at least 1986, and has a negative impact on patient care: we cannot make informed choices about treatments when the results of clinical trials are still being withheld from doctors, researchers, and patients. [3,4]

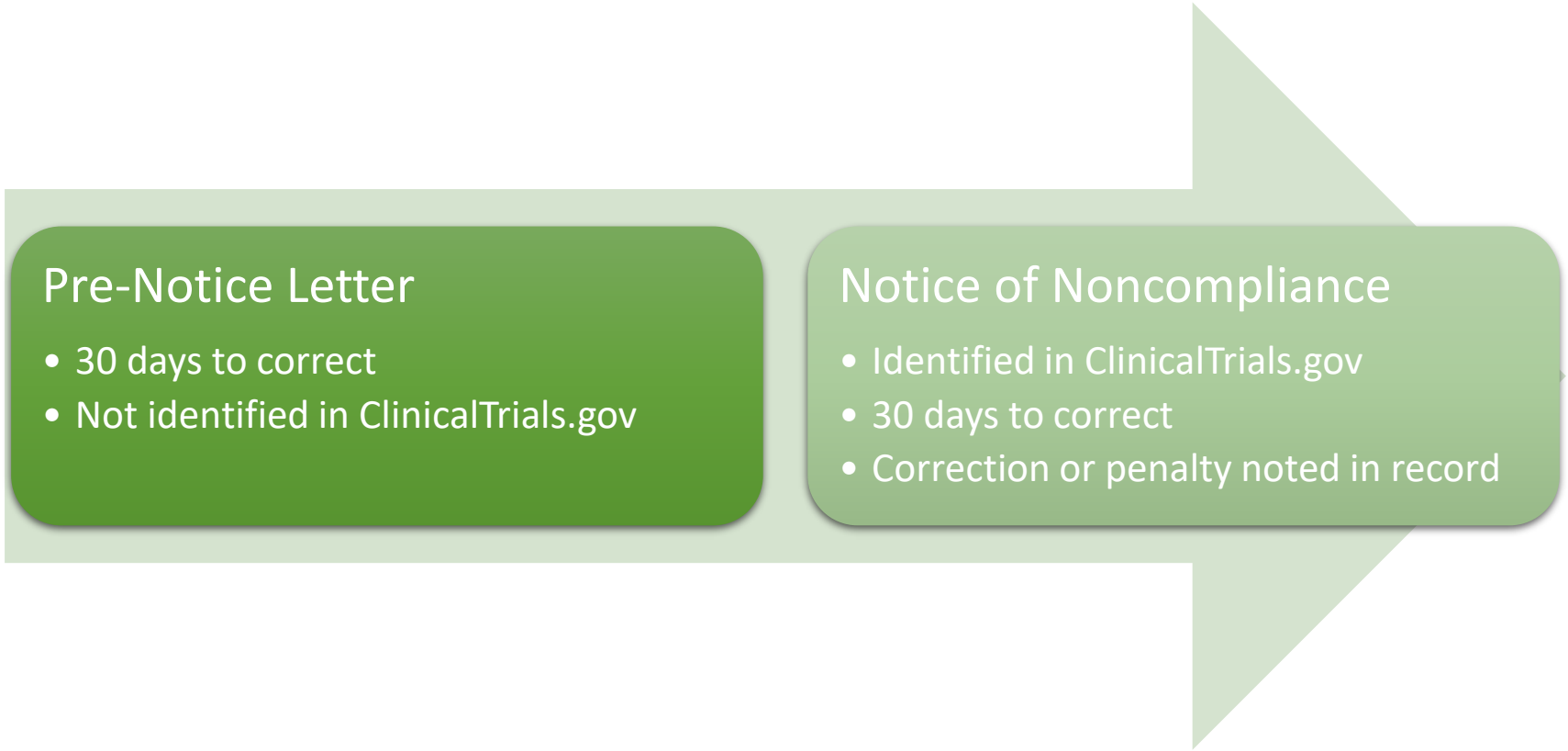
Here we describe a new regular initiative with *The BMJ*. Every week, we will publish a brief piece describing one important unreported trial that could be used to improve patient care. We hope that this will make the rather abstract issue of publication bias more concrete; shed light on the problem; provide a forum to discuss challenges and misunderstandings around trial reporting; and, ultimately, improve reporting rates.

https://blogs.bmj.com/bmj/2018/03/29/it-is-time-to-fix-the-problem-of-unreported-clinical-trials/

FDAAA 801 Violations field

- The FDAAA 801 Violation field identifies when FDA has issued a **Notice of Noncompliance** to the responsible party of an applicable clinical trial.
  - A Notice of Noncompliance indicates that the FDA has determined the responsible party was not in compliance with the registration or results reporting requirements for the clinical trial under the Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801).
  - Applies to Applicable Clinical Trials
- The National Library of Medicine (NLM) is required by FDAAA 801 to add information to a study record about any FDAAA 801 Violation.
- There are three categories of information that may be included:
  - Failure to submit required clinical trial information
  - Submission of false or misleading clinical trial information
  - Failure to submit primary and secondary outcomes
- Notice is sent to the Responsible Party identified in the ClinicalTrials.gov record
- **Pre-Notice Letters are not identified** as an FDAAA 801 Violation

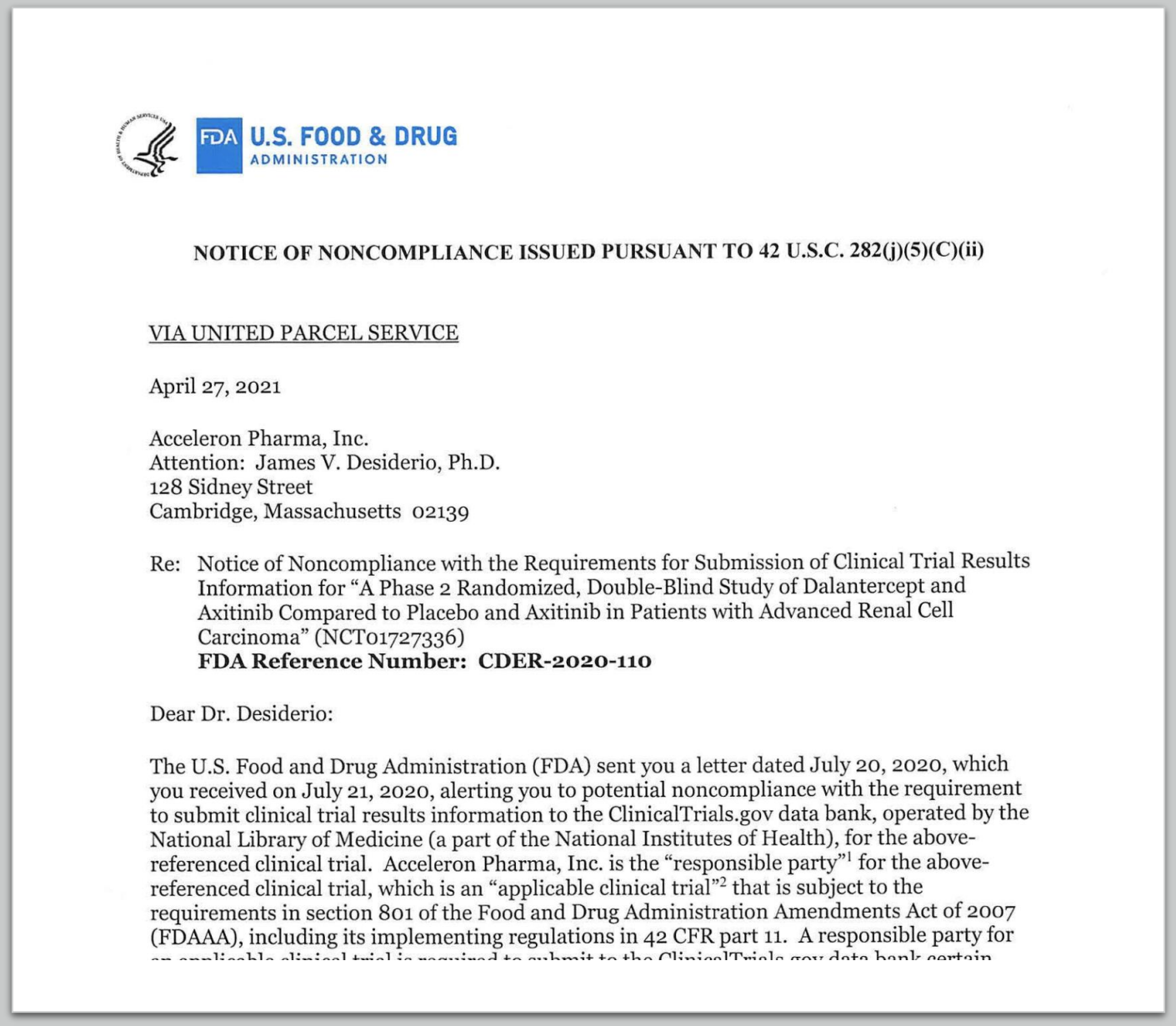
FDAAA 801 Violations field



Neither the public ClinicalTrials.gov website nor the PRS system includes information about Preliminary Notice of Noncompliance (Pre-Notice) Letters. Nor are Pre-Notice Letters posted on FDA's website. Pre-Notice Letters are sent to the responsible party for the applicable clinical trial. FDA obtains the responsible party's contact information from the PRS system.

Notice of Noncompliance Issued to Acceleron Pharma, April 27,2021: https://www.fda.gov/media/148036/download

FDA Statement, April 28, 2021: https://www.fda.gov/news-events/press-announcements/fda-takes-action-failure-submit-required-clinical-trial-results-information-clinicaltrialsgov



FDA U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE

April 27, 2021

Acceleron Pharma, Inc.
Attention: James V. Desiderio, Ph.D.
128 Sidney Street
Cambridge, Massachusetts 02139

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "A Phase 2 Randomized, Double-Blind Study of Dalantercept and Axitinib Compared to Placebo and Axitinib in Patients with Advanced Renal Cell Carcinoma" (NCT01727336)
FDA Reference Number: CDER-2020-110

Dear Dr. Desiderio:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 20, 2020, which you received on July 21, 2020, alerting you to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine (a part of the National Institutes of Health), for the above-referenced clinical trial. Acceleron Pharma, Inc. is the "responsible party"[1] for the above-referenced clinical trial, which is an "applicable clinical trial"[2] that is subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for

AllTrials

All Trials Registered | All Results Reported

Home | Find out more | Get involved | Supporters | News | **Sign the petition** | **Donate** | 🔍

What does all trials registered and reported mean?

AllTrials calls for all past and present clinical trials to be registered and their full methods and summary results reported.

Sign the petition

Donate to the campaign

Download this as a PDF here (310Kb). Italian and Russian translations of the AllTrials statement are also available.

What trial information needs to be registered and reported?

1. Registration
2. Summary results reporting
3. A full report
4. Individual patient data

www.alltrials.net/find-out-more/all-trials/

Clinical trials are investigations designed to assess the effects – wanted and unwanted – of healthcare interventions in people. The Declaration of Helsinki, which is the World Medical Association's statement of principles for medical research involving people, states that every investigator running a clinical trial should register it and report its results. Millions of volunteers have participated in clinical trials to help find out more about the effects of treatments on disease, yet that important ethical principle about reporting has been widely ignored. Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for good medicine, and trials being repeated.This is what led to the AllTrials campaign in January 2013, a campaign which is now supported by thousands of individual patients, clinicians and researchers across the world, and by hundreds of organisations representing millions of people.

FDAAA TrialsTracker

Single trials | Ranked sponsors | FAQ | Blog | Fund this work! | @FDAAATracker

an #AllTrials campaign

Who's sharing their clinical trial results?

FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively came into force for all trials due after January 2018. The FDA are not publicly tracking compliance. So we are, here.

Trials reported
7348 out of 10101

Percent reported
72.7%

US Govt could have imposed fines of at least
$19,601,530,235

Fines claimed by US Govt
$0

Filter trials by status:

On Overdue | On Overdue (cancelled results) | Off Ongoing | Off Reported | On Reported (late)

Search

Showing 1 to 100 of 5,508 entries

Status	Sponsor	Trial ID	Title	Completion date	Days overdue
overdue	City of Hope Medical Center	NCT02827877	Use of 64Cu-DOTA-Trastuzumab PET Imaging and Molecular Markers for Prediction of Response to Trastuzumab and Pertuzumab-Based Neoadjuvant Therapy [pACT]	2020-04-13	31
overdue	Ampel BioSolutions, LLC	NCT02598596	Tolerization Reduces Intolerance to Pegloticase and Prolongs the Urate Lowering Effect [pACT]	2020-04-13	31
overdue	University of Split, School of Medicine	NCT04226482	Comparison of Lateral Thermal Damage and Clinical Outcomes of Laparoscopic Appendectomy With New Versus Reused Ultrasonic Scalpel in Patients With Acute Appendicitis - Randomized Clinical Trial	2020-04-13	31

http://fdaaa.trialstracker.net/

ClinicalTrials.gov resources

- NIH News Release: HHS takes steps to provide more information about clinical trials to the public (September 16, 2016)
  - Zarin DA, Tse T, Williams RJ, Carr S. Trial reporting in ClinicalTrials.gov - the final rule. *N Engl J Med*. 2016 Nov 17;375(20):1998-2004.
  - Hudson KL, Lauer MS, Collins FS. Toward a new era of trust and transparency in clinical trials. *JAMA*; 2016 Oct 4;316(13):1353-1354.
  - Office of the Federal Register: Final Rule for Clinical Trials Registration and Results Information Submission (September 2016)
  - NIH: Changes from Current Practice Described in the Final Rule
  - Office of Management and Budget (OMB): EO 12866 Regulatory Review for Final Rule: OMB's Office of Information and Regulatory Affairs (OIRA) received the final rule on August 1, 2016, and concluded its review on Sep 15, 2016.
  - NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (Sep 2016)

ClinicalTrials.gov resources

- NIH OER: Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies With Human Participants (March 2021)
- Office of Human Research Protections (OHRP): Announcement: Federal websites that will satisfy the revised Common Rule's requirement to post clinical trial consent forms (45 CFR 46.116(h)) (August 2018)
- Zarin DA, Fain KM, Dobbins HD, et al. 10-Year Update on Study Results Submitted to ClinicalTrials.gov. N Engl J Med 2019 Nov 14 381;(20):1966-74. 2019.
- **Data sharing resources**
  - http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf
  - http://www.icmje.org/news-and-editorials/proposed-disclosure-form.pdf
- http://www.bumc.bu.edu/ohra/clinicaltrials-gov/
- https://clinicaltrials.gov/

Thank you!

- The researchers and their team members
- The CRS attendees

- Matt Ogrodnik
- Jami Wood
- Mary-Tara Roth
- Diana Lehman
- John Ennever
- Fanny Ennever