

ClinicalTrials.gov Modernization Public Meeting

April 30, 2020



National Library of Medicine

ClinicalTrials.gov Modernization

Rebecca J. Williams, Acting Director of ClinicalTrials.gov

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.



Carrie D. Wolinetz, PhD

Associate Director for
Science Policy, NIH

Welcome and Introduction

General Agenda

- 9:30 a.m. Welcome and Introduction
- 9:45 a.m. Overview of ClinicalTrials.gov Modernization Effort and High-level Summary of Request for Information (RFI) Public Comments
- NLM Welcome and Introduction to Board of Regents Public Service Working Group
- 10:30 a.m. Information Submission Panel
- 11:15 a.m. Break
- 11:30 a.m. Website Functionality Panel
- 12:20 p.m. Summary and Next Steps
- 12:30 p.m. Adjourn



**Rebecca J.
Williams,
PharmD, MPH**

Acting Director of
ClinicalTrials.gov

Overview of ClinicalTrials.gov Modernization Effort

Goals of the Public Meeting

Provide an overview of ClinicalTrials.gov Modernization

Share high-level summary of Request for Information (RFI) comments and key themes

Gather diverse stakeholders to share interests and needs

Obtain further information on RFI themes and topic areas

Imagine you are here!
NIH Natcher Conference
Center
Bethesda, MD

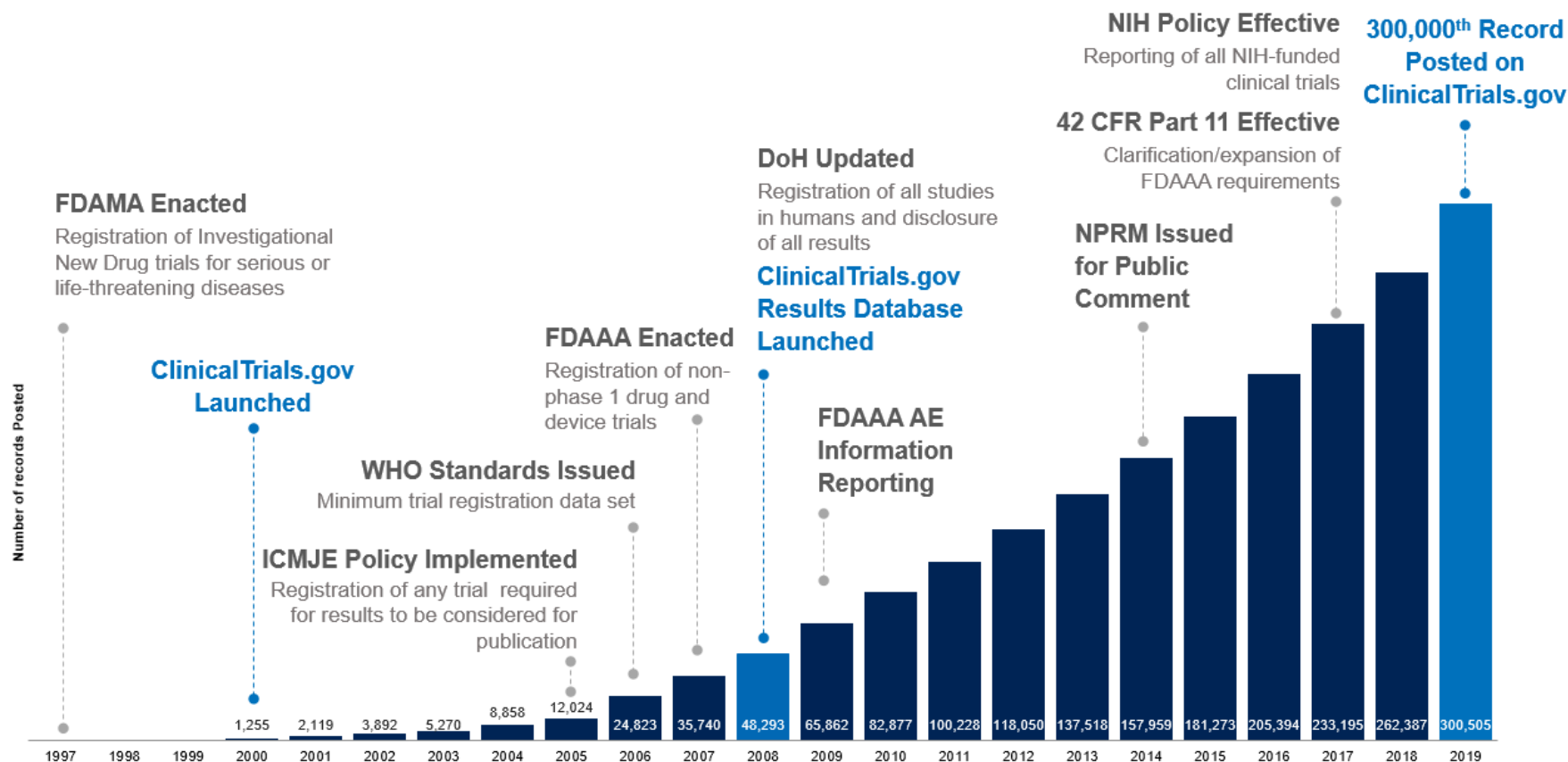


Overview

330,000+
registrations

42,000+
posted results

3.5 million
visitors monthly



Abbreviations: AE, adverse event; CFR, Code of Federal Regulations; DoH, Declaration of Helsinki; FDAAA, Food and Drug Administration Amendments Act; FDAMA, Food and Drug Administration Modernization Act; ICMJE, International Committee of Medical Journal Editors; NIH Policy, NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information; NPRM, Notice of Proposed Rulemaking; and WHO, World Health Organization.

Benefits of Comprehensive Registration and Results Reporting

All contribute to increased public trust in clinical research

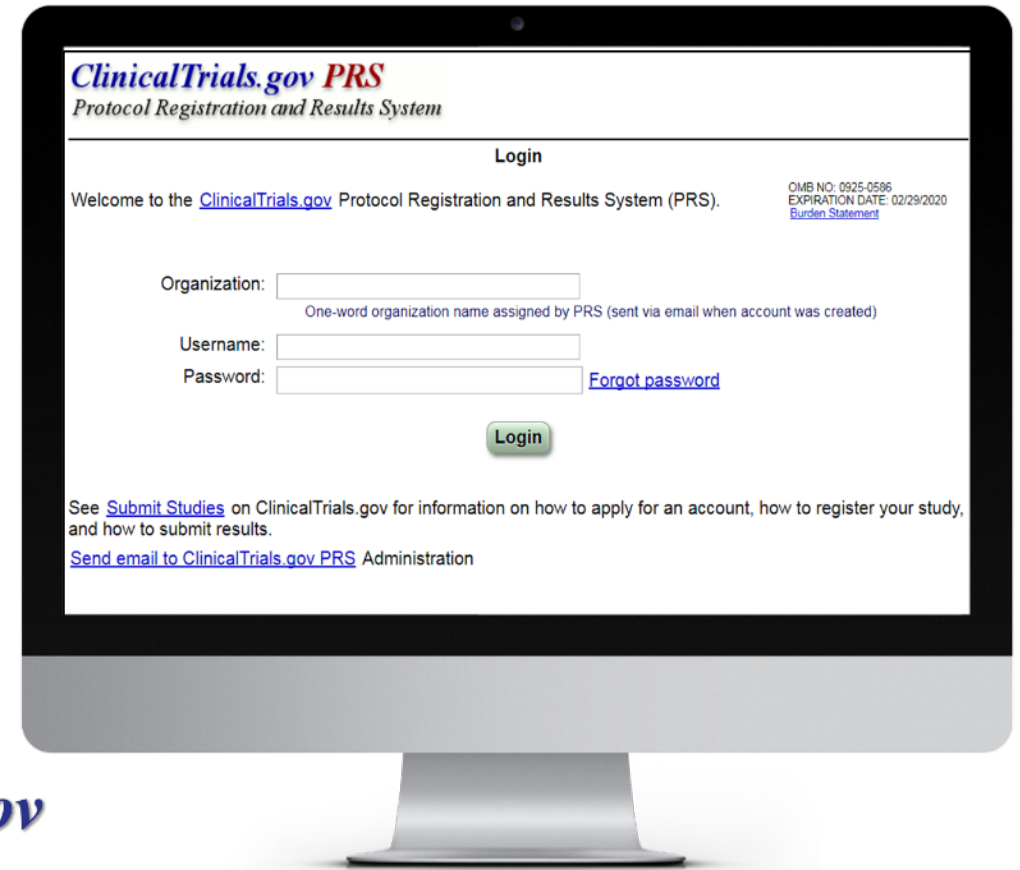
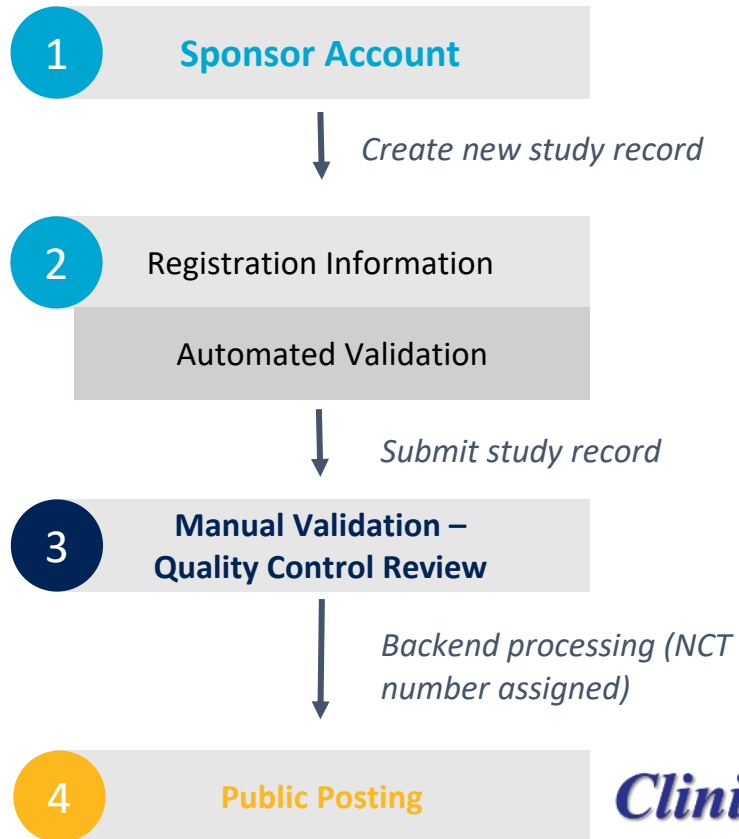
- Honor commitment to participants that their contributions will advance science; support enrollment
- Mitigate publication bias
- Advance stewardship and accountability
 - Identify unmet research needs
 - Facilitate complete reporting
 - Avoid unnecessary study duplication
 - Evaluate research integrity
- Support evidence-based medicine

| ClinicalTrials.gov Aims

Two primary aims in support of realizing the intended benefits of comprehensive registration and results reporting

- Aim 1: Collect complete and informative information about clinical studies
- Aim 2: Facilitate use of information to help the public and researchers find studies of interest

Aim 1: Collect complete and informative information about clinical studies



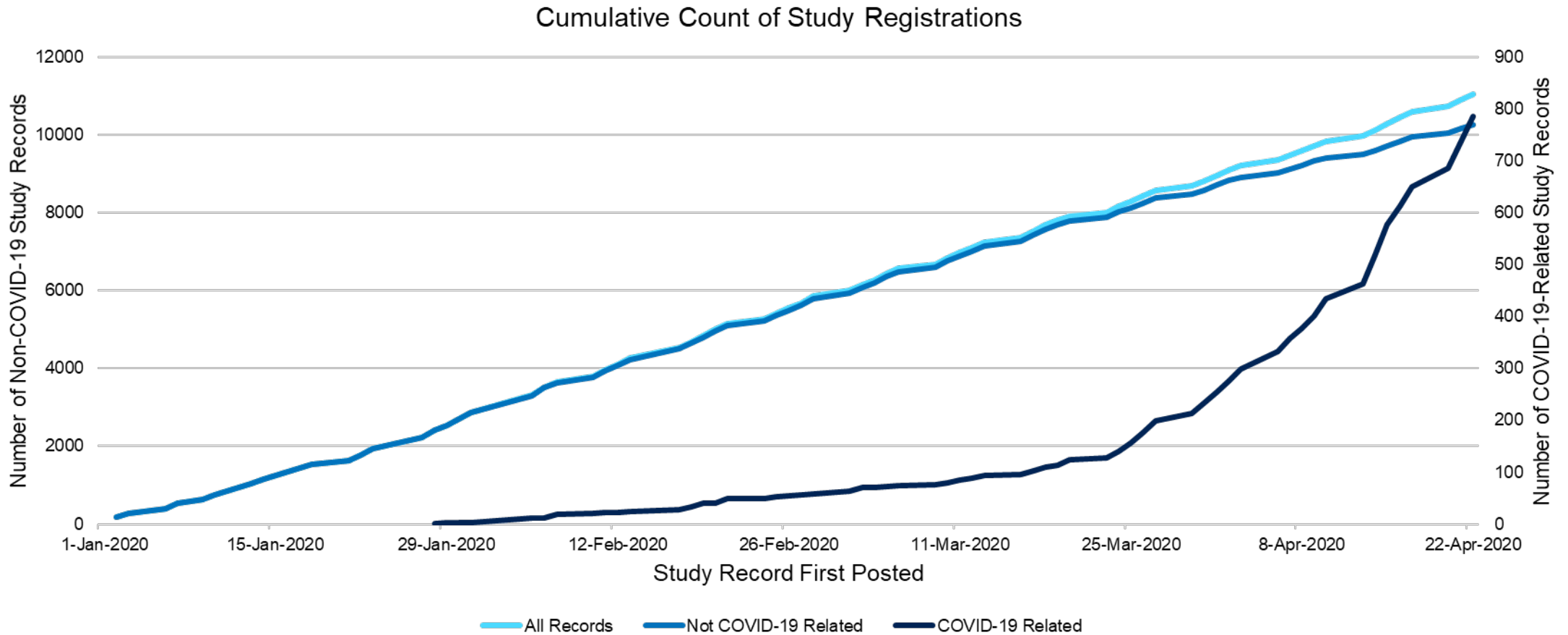
ClinicalTrials.gov

Submission Review Process and Volume

- Automated validation rules detect issues before submission
- Manual quality control (QC) review after submission focuses on identifying apparent errors, deficiencies, or inconsistencies
- NLM staff review registration study records within 2 to 5 days
 - ~ 1,200 new registration records per week (includes new records and previously reviewed records that did not meet QC review criteria)
 - ~ 6,600 updated registration records per week
- NLM staff review all results study records < 25 days
 - ~ 280 new results records per week (includes new records and previously reviewed records that did not meet QC review criteria)
 - ~ 140 updated results records per week

Overall and COVID-19-Related New Study Registrations

Jan 1, 2020 – Apr 22, 2020



Submission Support Materials

- PRS User's Guide
- PRS Guided Tutorials (shown on right)
- Data Element Definitions
- Templates and Submission Checklists
- Study Design Examples
- Frequently Asked Questions (FAQs)
- Legal, Regulatory, and Policy Requirements Information

ClinicalTrials.gov PRS Protocol Registration and Results System PRS Guided Tutorials

4%

- Introduction
- Preparing to Enter Results
- Entering Participant Flow Information
- Entering Baseline Characteristics Information
- Entering Outcome Measure and Statistical Analysis Informa...
- Entering Adverse Event Information
- Entering Limitations and Caveats
- Entering More Information: Certain Agreements and

this information is translated is shown here in the CONSORT Flow Diagram to Participant Flow Table Crosswalk.

CONSORT Diagram to Participant Flow Table Crosswalk

Parallel Study Design Example CONSORT Flow Diagram

Assessed for Eligibility N = 205

Excluded N = 5
Did not meet inclusion criteria

Randomized N = 200

Remained N = 175
Discontinued N = 21
Completed N = 154

Reasons for Discontinuation:
Adverse Event: 5
Withdrawal by Subject: 2
Protocol Violation: 2
Lack of Efficacy: 1
Physician Decision: 1
Lost to Follow-up: 1
Pregnancy: 1

Placeno N = 95
Discontinued N = 18
Completed N = 77

Reasons for Discontinuation:
Adverse Event: 8
Withdrawal by Subject: 4
Protocol Violation: 2
Lack of Efficacy: 1
Physician Decision: 1
Lost to Follow-up: 2

ClinicalTrials.gov Participant Flow Table

Participants were enrolled based on protocol version at 3 academic medical centers in 2007-2008, 2011, and January 2016. The 2007-2008 enrollment of 205 enrolled participants, 202 met inclusion criteria and were randomized to treatment.

Assignment Status	Participants without randomization	Participants without randomization under inclusion	Participants without randomization under exclusion
Pre-assignment Date			
Assignment Date			
Participant Flow			
Randomized	200	0	0
Discontinued	21	18	3
Completed	154	77	77
Total	175	95	80

Resources

Before entering information in the Participant Flow module, use these resources to help you gather and organize the information you will need:

- [Participant Flow Data Preparation Checklist](#)
- [Participant Flow Template](#)
- [Results Data Element Definitions—Participant Flow](#)

You can also refer to the [Results Quality Control Review Criteria](#), which will help you

COVID-19: Submitter Information

Issued new support materials to address top questions (updated as needed)

- <https://prsinfo.clinicaltrials.gov/TopQuestionsFromResponsibleParties-Covid19.pdf>

What's New

2020

April 2, 2020

- **Answers to Questions from Responsible Parties on Submitting Information to ClinicalTrials.gov Related to Coronavirus (COVID-19) Available:** Questions about submitting information to the ClinicalTrials.gov Protocol Registration and Results System (PRS) have been addressed in [Responses to Top Questions from Responsible Parties Related to Coronavirus \(COVID-19\)](#) (PDF). COVID-19 is an emerging, rapidly evolving situation. These responses will be updated as needed. Document is available on the [Support Materials](#) page.

ClinicalTrials.gov

*ClinicalTrials.gov is a service of the
National Institutes of Health.*

Responses to Top Questions from Re

NOTE: COVID-19 is an emerging, rapidly evol

NIH recognizes that the COVID-19 public hea availability of organizations and staff for res information to ClinicalTrials.gov. These resp face with managing clinical trial information System (PRS).

Responsible Parties have asked about updati evolving situation. We reinforce the importa information available to the public on Clinica However, due to the potential exceptional in staff availability, NIH acknowledges that del expect clinical trial information to be update delays are resolved and recommend that sp allow for determination of the appropriaten

1) How do Responsible Parties update the c recruitment status of individual sites that cl

Responsible Parties should update the [Query records](#). For more information, see the [FAQ](#).

To help ensure that accurate up-to-date clini necessary changes to recruitment status on! Refer to [the list of recruitment status option](#) on the specific situation for your study. Whe Recruiting, the Individual Site Status data ele Recruitment Status applies to each individua Withdrawn as Overall Recruitment Status, yt study was stopped as part of the [Why Study](#).

You may also provide additional information element. When doing so, please include the

2) How does the Sponsor update a study re Responsible Party is not available?

If the Principal Investigator designated by th to update the record, then the Sponsor can Responsible Party data element on the Edit Administrator for your organization can ther

3) How can Responsible Parties for studies related to COVID-19 make their study records easily searchable?

Please include the World Health Organization (WHO) official acronym, COVID-19, in the [Brief Title](#) of records for studies that relate to the virus that causes COVID-19, known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This will allow for easier identification of studies related to COVID-19. If the study is not related to SARS-CoV-2, please do not mention COVID-19 in the Brief Title.

Coronavirus (COVID-19): Top Questions

Coronavirus (COVID-19): Top Questions

02 April 2020

Aim 2: Facilitate use of information to help the public and researchers find studies of interest

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 331,715 research studies in all 50 states and in 209 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the risks and [potential benefits](#).

Find a study (all fields optional)

Status ⓘ
 Recruiting and not yet recruiting studies
 All studies

Condition or disease ⓘ (For example: breast cancer)

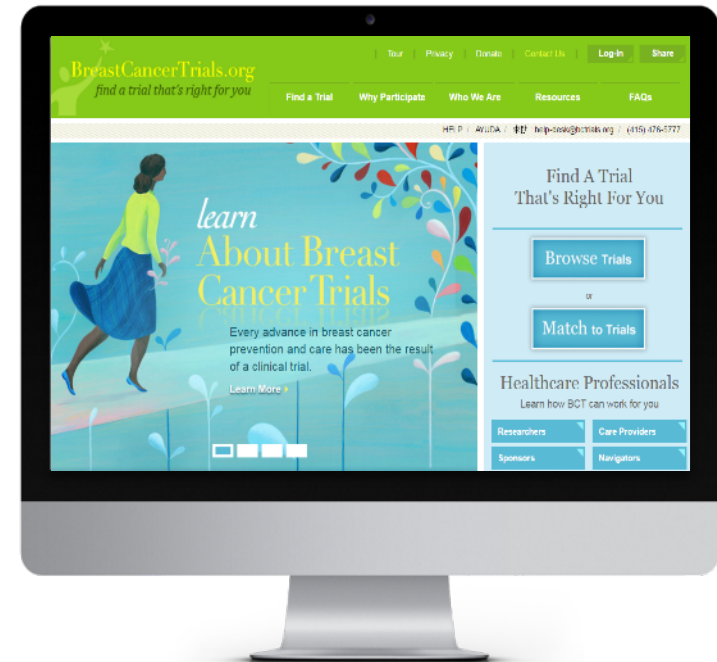
Other terms ⓘ (For example: NCT number, drug name, investigator name)

Country ⓘ

[Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

ClinicalTrials.gov API



Website Use by the Numbers

ClinicalTrials.gov
Search Statistics:

This year

10.2
million clicks

Compared to Last Year

7.7 million
clicks



This year

65.6 million
page visits

13.1 million
users

20.9 million
sessions

Last Year

46.8 million
page visits

9.1 million
users

15 million
sessions

COVID-19: Added related resources and link to registered studies

COVID-19 is an emerging, rapidly evolving situation.
Get the latest public health information from CDC: <https://www.coronavirus.gov>.
Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 336,444 research studies in all 50 states and in 210 countries.

See [listed clinical studies](#) related to the coronavirus disease (COVID-19)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Find a study (all fields optional)

Status ⓘ

Recruiting and not yet recruiting studies
 All studies

Condition or disease ⓘ (For example: breast cancer)

X

Other terms ⓘ (For example: NCT number, drug name, investigator name)

X

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

Home > Search Results

Modify Search Start Over +

902 Studies found for:
COVID-19

Also searched for
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](#)
- **CDC:** [Information for Clinicians on Therapeutic Options for COVID-19 Patients](#)

COVID-19: 3rd Party Website Examples

Covid-19 TrialsTracker
Tracking COVID-19 Trials and their Results

Full Data Results **Interactive** Figures About

Covid-19 Trials Tracker

Recruitment Status
■ Not Recruiting
■ Recruiting

Study filters:
 Study Type: (All)
 Recruitment Status: (Multiple values)
 Phase: (All)
 Intervention Type: (All)

Trialid	Has Results	Feb 1	Mar 1	Apr 1	May 1
ChiCTR2000029308	True				
ChiCTR2000030315	False				
ChiCTR2000030390	False				
ChiCTR2000030762	False				
ChiCTR2000030784	False				
ChiCTR2000030301	False				
ChiCTR2000030302	False				
ChiCTR2000030303	False				
ChiCTR2000030304	False				
ChiCTR2000030305	False				
ChiCTR2000030306	False				
ChiCTR2000030307	False				
ChiCTR2000030308	False				
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ChiCTR2000030350	False				

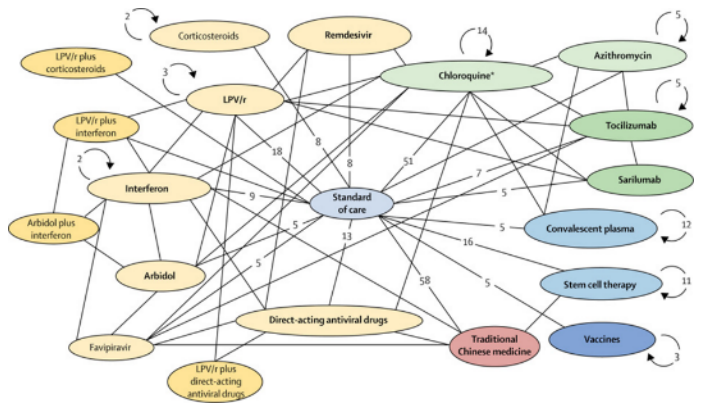
ChiCTR2000030301
 Trial ID: NCT04279795 (ClinicalTrials.gov)
 Date enrollment: 1/20/2020
 Date registration: 2/19/2020
 Recruitment Status: Recruiting
 Study Type: Observational
 Phase: Phase 1
 Title: Detection of 2019 Novel Coronavirus in Multiple Organ System and Its Relationship With Clinical Manifestations
 Duration: 91

Source register: (All)
 Countries: (All)
 Sponsor: (All)

Clinical Trial Connect

DEEP 6 AI

A real-time dashboard of clinical trials for COVID-19
 Kristian Thorlund · Louis Dron · Jay Park · Grace Hsu · Jamie Forrest · Edward J Mills



anticovid
by inato

SubjectWell

Government of Canada / Gouvernement du Canada

REAGAN-UDALL FOUNDATION
for the Food and Drug Administration

Cochrane COVID-19 Study Register
Trusted evidence. Informed decisions. Better health.

NIH does not endorse or recommend any commercial products, processes, or services.

COVID-19: Landscape Analysis

Ongoing Clinical Trials for the Management of the COVID-19 Pandemic.

PMID: 32291112 PMC7144665

Apr 16, 2020

Lythgoe, Mark P; Middleton, Paul • Trends Pharmacol Sci

Full Text

TREATMENT



COVID-19 has rapidly developed into a worldwide pandemic with a significant health and economic burden. There are currently no approved treatments or preventative therapeutic strategies. Hundreds of clinical studies have been registered with the intention of discovering effective treatments. Here, we review currently registered interventional clinical trials for the treatment and prevention of COVID-19 to provide an overall summary and insight into the global response.

Keywords:

#2019-ncov #covid-19 #sars-cov-2 #coronavirus #pandemic

Trends in Pharmacological Sciences

Available online 9 April 2020

In Press, Corrected Proof



TABLE

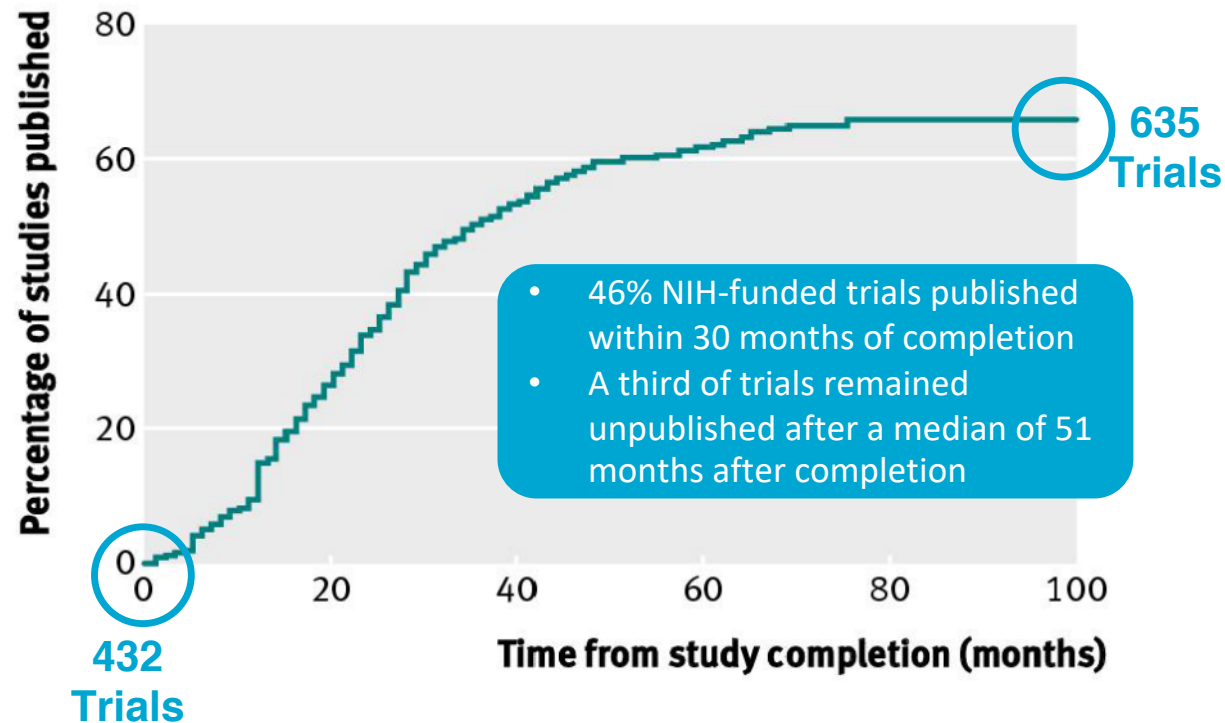
Table 1, Key Table: Ongoing Clinical Trials for treatment (A) and prevention (B) of COVID-19 (current as of March 20th, 2020)

Table 1A: Ongoing Clinical Trials for Treatment of COVID-19

Clinical Trial ID (Registry)	Intervention	Size ^A	Randomised	Blinded	Status	Country of Origin (Pharma Sponsor)
Antiviral						
NCT04292899 (ClinicalTrials.gov)	Arm A: Remdesivir Arm B: Standard Treatment	400	Yes	No	Recruiting	USA & Asia (Gilead)
NCT04292730 (ClinicalTrials.gov)	Arm A: Remdesivir Arm B: Standard Treatment	600	Yes	No	Recruiting	US & Asia (Gilead)
NCT04280705 (ClinicalTrials.gov)	Arm A: Remdesivir Arm B: Placebo	394	Yes	Double	Recruiting	USA South Korea
2020-000841-15 (EU-CTR)	Arm A: Remdesivir Arm B: Standard Treatment	400	Yes	No	Recruiting	Worldwide (Gilead)
2020-000842-32 (EU-CTR)	Arm A: Remdesivir Arm B: Standard Treatment	600	Yes	No	Recruiting	Worldwide (Gilead)

Mitigate Publication Bias

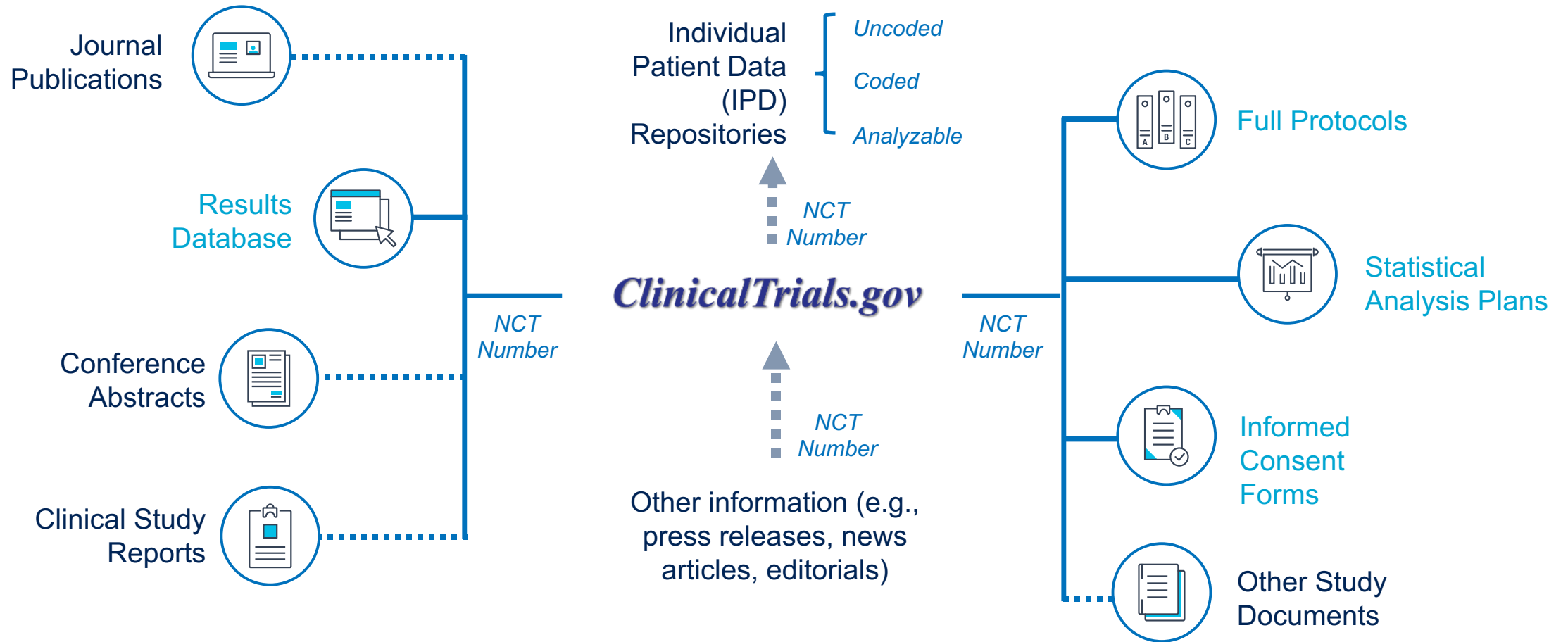
Publication of NIH-Funded Clinical Trials
(Ross et al. *BMJ* 2012)



ClinicalTrials.gov is a unique source of results

- ~ 50% of posted results are not yet published in a journal
—Zarin et al. *N Engl J Med* 2011

ClinicalTrials.gov: Information Scaffold



| ClinicalTrials.gov Modernization

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.

| Who is Modernization for?



Internal

Information specialists,
reviewers, developers

Management, policy, oversight



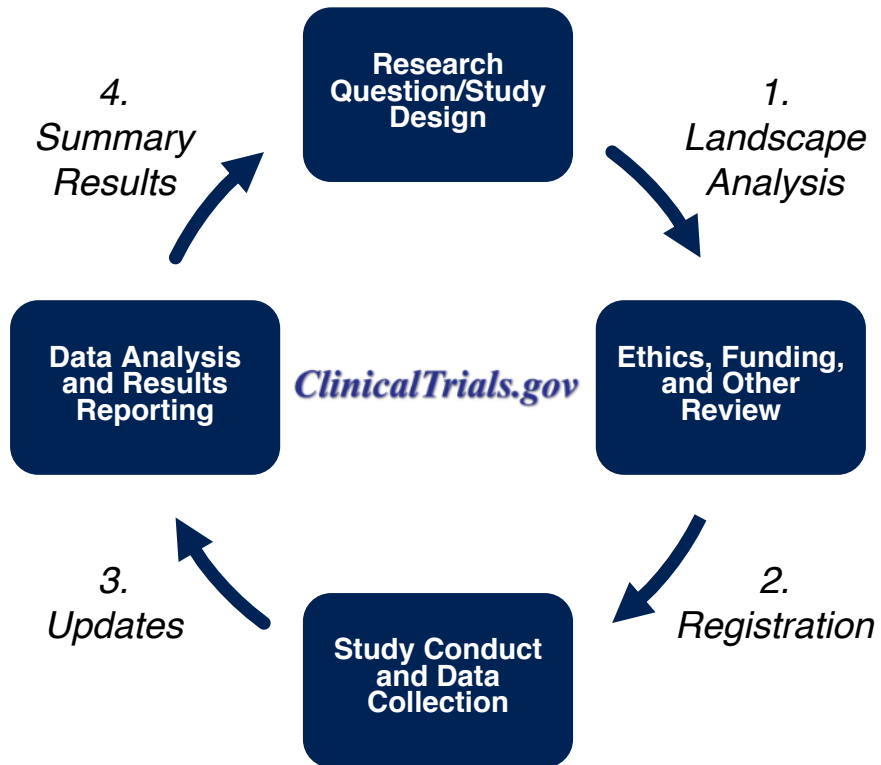
External

Patients, healthcare providers,
and related organizations

Data submitters (investigators,
sponsors, 3rd party services)

Researchers and journal
editors

ClinicalTrials.gov Modernization Overview



Current year: Engagement

- Engage with stakeholders to determine and validate approach and specifications
 - Request for Information (RFI) and Public Meeting
- Develop modernization roadmap
- Enhance internal business processes

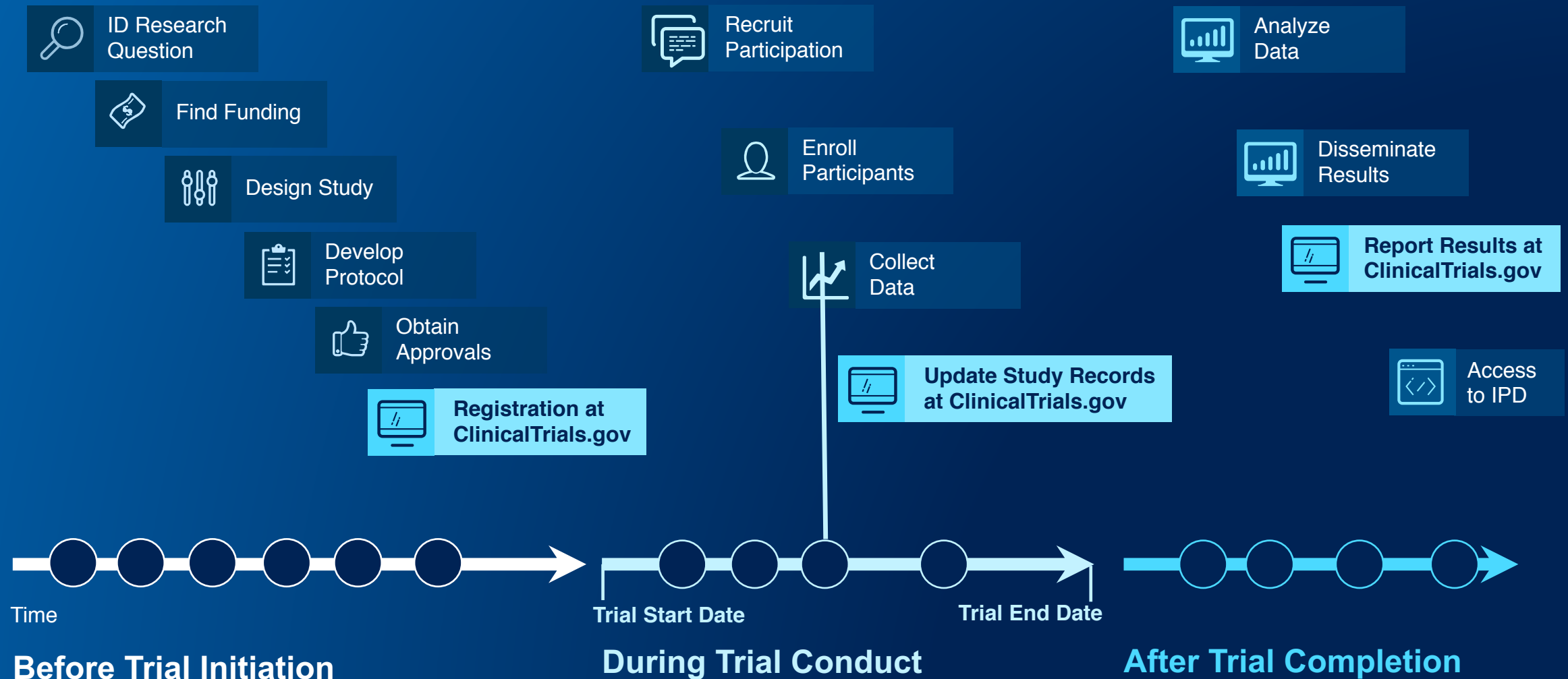
Future (years 2 – 5): Implementation

- Implement modernization roadmap
 - User testing/evaluation and continue engagement
 - Improvements to support compatibility across clinical trial lifecycle (seamless end-to-end process)
 - Upgrade system infrastructure components

Infrastructure Accomplishments 2020

- Migrated development, test, and production environments from NLM's Lister Hill National Center for Biomedical Communications to NLM's National Center for Biotechnology Information (NCBI)
 - Note: ClinicalTrials.gov program was organizationally shifted several years ago
- New server hardware
- Upgraded operating system, servers, version control system, software components, database
- Adopted NCBI security posture, including network, firewall, and patching methodology
- Pilot projects to evaluate cloud infrastructure approaches

Clinical Trial Lifecycle Opportunities





Patricia Flatley Brennan, RN, PhD

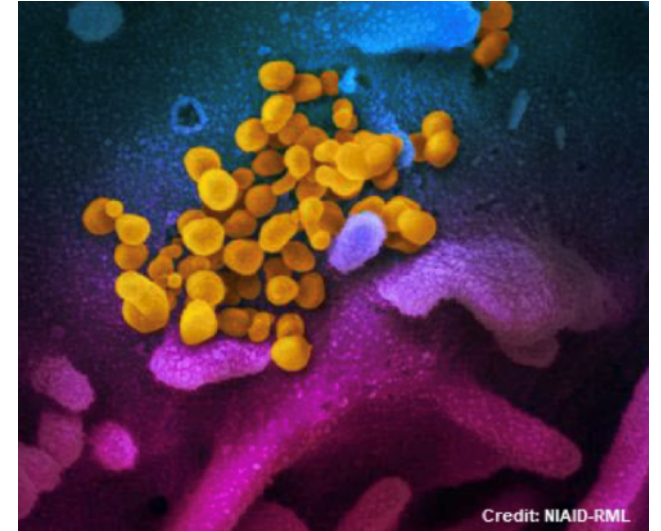
Director of National Library
of Medicine (NLM)

NLM Welcome and Introduction to Board of Regents Public Service Working Group



NLM Response to COVID-19: Resources

- **PubMed Central**
 - Expanding access to ~ 40k AI-ready articles, 2M accesses
- **Exploiting machine-readable COVID-19 literature**
 - Kaggle - challenge AI-fueled insights from literature
 - TREC-COVID challenge to search engines
 - LitCOVID - AI-curated literature hub organizing and exploring scientific information
- **ClinicalTrials.gov**
 - > 900 clinical studies
 - Display of studies listed in WHO portal with > 900 studies
- **GenBank**
 - Fully automated 24-hour submission and release of data
- **Standards and Terminologies**
 - C19 updates to UMLS, MeSH, RxNorm, LOINC, Common Data Elements Repository, VSAC
- **NLM support of libraries virtually engaging their communities**



Enhancing Access to COVID-19 Literature and Molecular Data Resources

Developing and strengthening infrastructure, mechanisms, and tools to **ensure continued access to high quality literature** when libraries are closed during public health events

Supporting chemical editing for **MeSH** and **ChemIDplus** to cover COVID-19/Coronavirus SARS/MERS-related drugs and chemicals

Ensuring **NLM Collection Materials for COVID-19** are available electronically

Extending **PMC** submission workstreams to facilitate AI/machine learning

Developing a **PubMed** portal for COVID-19 literature collected through **LitCOVID** text mining

Ensuring rapid sequence submission and access through **GenBank** and **VirusHub**

Using **SRA** in the cloud for viral surveillance and discovery

Improving Quality of Clinical Data for Research and Care

- Implementation guidelines, training for standardization, and addition of codes to support COVID-19-related laboratory tests within LOINC
- Value Set Authority Center (VSAC) FHIR API development to enable standardized sharing of COVID-19 terminology updates

Accelerating Research: Deep Phenotyping, Text-mining, and Real-time Surveillance

- Mining clinical data for ‘deep phenotyping’ models that can be used to identify or predict presence of COVID-19
- AI/Machine Learning, analytics, and visualization of image and clinical data to support clinical decisions in real time
- Public health surveillance using virus genomics, health data, and social media data to identify spread

National Library of Medicine Board of Regents

The NLM Board of Regents was established in 1956 by the same Act that created the National Library of Medicine.

Serves as advisory body to the Secretary, HHS

Serves as advisory body to the Assistant Secretary for Health and others

Meets three times a year

Summary of Working Group Charge

The NLM Board of Regents Public Service Working Group is charged to explore topics related to ClinicalTrials.gov modernization such as, but not limited to, ways NLM can:

Maintain the *integrity* of ClinicalTrials.gov as a trusted resource

Maximize the *utility* of the growing corpus of information

Connect with stakeholders through *engagement* to ensure evolving needs are understood and considered

Report regularly in open session to the NLM Board of Regents



Carlos R. Jaén, MD, PhD

Working Group Chair
University of Texas Health
Science Center at San
Antonio

“ Thanks everyone for joining the meeting today, we are excited about this initiative. At a time when robust science needs to inform our path forward, our task is more important than ever. [ClinicalTrials.gov](https://clinicaltrials.gov) is a powerful tool to help us evaluate clinical evidence. Our modernization efforts must be focused on you and all the stakeholders you represent. Let’s make the most of our time together today.”

NLM Board of Regents

Public Service Working
Group on ClinicalTrials.gov
Modernization



**Rebecca (Becky) J.
Williams, PharmD,
MPH**

Working Group Executive
Secretary

National Library of Medicine,
NIH



**Lourdes Baezconde-
Garbanati, PhD, MPH**

University of Southern
California

NLM Board of Regents

Public Service Working
Group on ClinicalTrials.gov
Modernization



**Kent J. DeZee, MD,
MPH, FACP, COL, MC**

U.S. Army Office of the
Surgeon General



**Gary A.
Puckrein, PhD**

National Minority Quality
Forum

NLM Board of Regents

External Members

Public Service Working
Group on ClinicalTrials.gov
Modernization



**Carrie Dykes,
PhD**

University of Rochester
Medical Center



**Alissa Gentile,
MSN, RN**

The Leukemia and
Lymphoma Society



**Sally A. Gore, MS,
MS LIS**

University of Massachusetts
Medical School



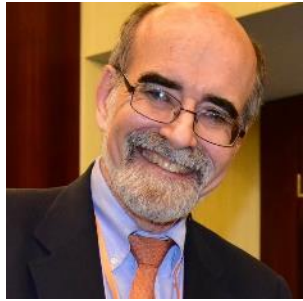
**Barbara Kress,
BSN, RN**

Merck

NLM Board of Regents

External Members

Public Service Working
Group on ClinicalTrials.gov
Modernization



**Seth A. Morgan,
MD**

National Multiple Sclerosis
Society



**Joseph S. Ross,
MD, MHS**

Yale School of Medicine



**Stephen J.
Rosenfeld, MD, MBA**

Secretary's Advisory Committee
on Human Research
Protections (SACHRP)



**Steven Woloshin,
MD**

The Dartmouth Institute

NLM Board of Regents

*Ex Officio NIH
Members*

Public Service Working
Group on ClinicalTrials.gov
Modernization



**Lyric A. Jorgenson,
PhD**

Office of Science Policy

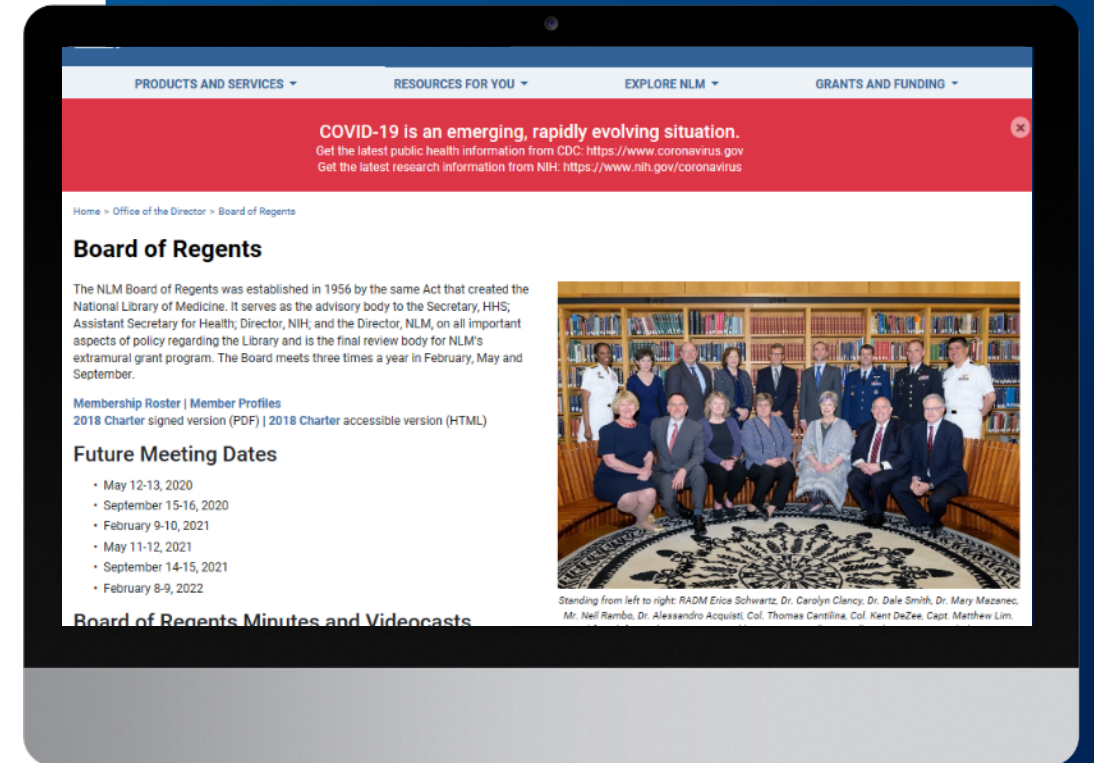


**Pamela Reed
Kearney, MD**

Office of Extramural Research

Learn More

Additional link to materials for NLM Board of Regents and the Public Service Working Group on ClinicalTrials.gov Modernization
<https://www.nlm.nih.gov/od/bor/bor.html>





**Rebecca J.
Williams,
PharmD, MPH**

Acting Director of
ClinicalTrials.gov

High-level Summary of Request for Information (RFI) Public Comments

Request for Information (RFI): ClinicalTrials.gov Modernization

Goal: To obtain public input to guide the National Library of Medicine (NLM) in planning infrastructure enhancements aimed at users and submitters of ClinicalTrials.gov

Timing: 75-day comment period (Dec 30, 2019 – Mar 14, 2020)

Collection Method: Web-based form with 3 main topic areas and 11 specific sub-question prompts; upload of attachments also permitted

Guide Notice (NOT-LM-20-003):
<https://grants.nih.gov/grants/guide/notice-files/NOT-LM-20-003.html>

Overview of RFI Main Topic Areas

Note: RFI not intended to modify existing legal and policy requirements for clinical trial registration and results submission

1

Website functionality of ClinicalTrials.gov website and application programming interface (API)

2

Information submission using the ClinicalTrials.gov Protocol Registration and Results System (PRS)

3

Data standards that may support submission, management, or use of information content

RFI Informed by Input from NIH

NLM held **12 sessions** with **20 Institutes and Centers (ICs)** from July to Dec 2019

Shared current status and general plans for ClinicalTrials.gov modernization

Requested input on issues important to ICs

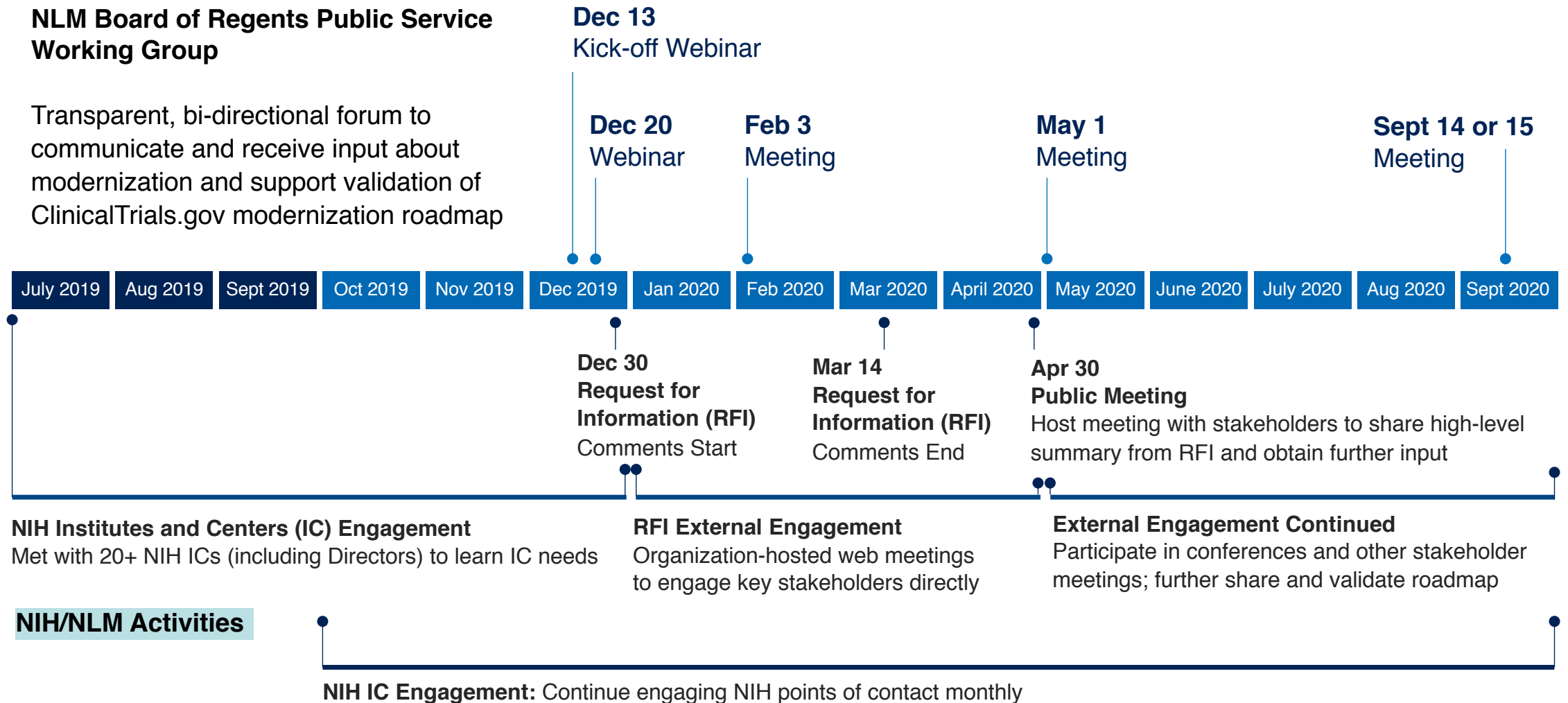
High-Level Themes from NIH IC Sessions

- **Engagement** – ensure broad representation
- **Mission** – clarify and enhance communication re: benefits of reporting
- **Inclusion** – reinforce importance and standardize reporting
- **Value** – participant enrollment and scientific aspects of clinical research lifecycle
- **Study-specific issues** – for example, basic science, observational/natural history
- **Results submission** – address challenges
- **Systems and standards** – integration and discovery with NIH systems; data standards

Modernization External Activities FY2020

NLM Board of Regents Public Service Working Group

Transparent, bi-directional forum to communicate and receive input about modernization and support validation of ClinicalTrials.gov modernization roadmap



| RFI External Engagement Strategy January – April 2020

Directly inform stakeholders of modernization effort and opportunity to submit comments to RFI

Audience

- Patients, Advocacy and Healthcare Providers
- Investigators and Sponsors
- Researchers and Journal Editors

Core Materials

- Request for Information (RFI) Guide Notice
- NLM and NIH OER Blogs
- Modernization Banner and Webpage

Method

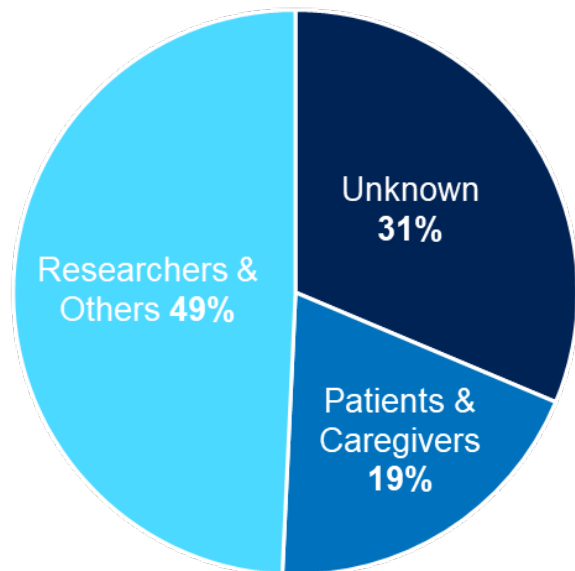
- Targeted Emails
- Public Webinars
- Social Media
- *Hot Off the Press!* e-bulletin
- Organization Meetings
- Stakeholders
- Public Meeting

Reach

- 3,000+ subscribers to e-bulletin
- 1,200+ webinar participants
- Direct emails to 60+ organizations
- Over 10 web meetings hosted by organizations

RFI Comments by Role

268 submissions received;
apparent role of submitter
assigned by NLM reviewer



Breakdown of Roles

Patients & Caregivers	Percent	Number
Friend, Family, Advocate of Patient	56%	29
Patient	31%	16
Health Care Provider	13%	17

Researchers & Others	Percent	Number
Data Provider	58%	76
Scientist/Researcher	27%	35
Other (e.g., IRB)	11%	14
Clinical Research Support	4%	5
Medical Librarian or Info. Specialist	2%	2

RFI Comments Initial Analysis Approach

- Downloaded all comments
 - Note: Full comment set available on [ClinicalTrials.gov Modernization](https://clinicaltrials.gov/modernization) webpage
- Review of comments performed by NLM subject matter experts
- Developed high-level “domain codes” and lower-level “issue codes” based on review of responses; approximately 200 domain-issue code pairs
- Assigned one or more domain and issue code pairs to each response; assignment also reviewed by a second reviewer
- Summarized number of responses by domain and issue code

Number of Respondents by Sub-question (259 unique respondents)



Value: Sentiments Expressed in Comments

“

The ClinicalTrials.gov site provides an important public service, and it's invaluable to have the registry information freely available to the public. As the ClinicalTrials.gov platform continues to evolve, in both form and function, it will become even more widely used and beneficial to the patient, research, and funding communities. Thank you for your efforts on this project!”

Example: Comments from Different Roles

Contact information for
study sponsors and
sites

“

Need to ensure sponsors provide the name of each institution participating in a trial (not just a postcode), along with the name of the investigator at that site, and an email address to contact him/her or their delegate”

“Clinical trials.gov is a huge headache for PI's in resource-limited small towns... All I get from ClinicalTrials.gov is emails from people from other regions of the country/world (who are ineligible to participate) inquiring if they can participate in my study which takes even more of my time.”

Coming Up...

10:30 a.m. – 11:15 a.m.

Information Submission Panel

- Heather Dobbins, ClinicalTrials.gov
- Carrie Dykes, University of Rochester Medical Center
- Sally A. Gore, University of Massachusetts Medical School
- Barbara Kress, Merck

Panels

