RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

Keeping Up with ClinicalTrials.gov: A Systematic Approach in Maintaining Compliance

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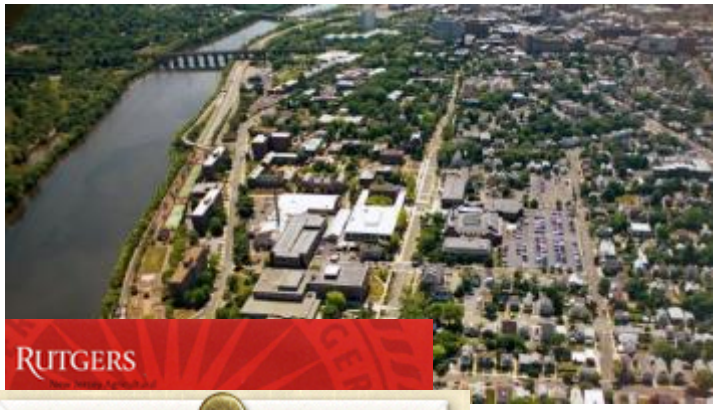
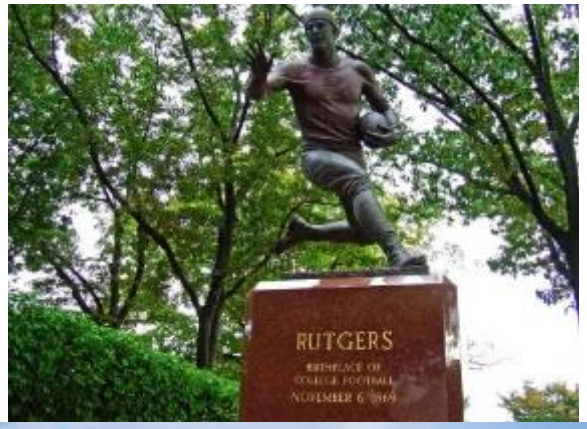
Office of Research and Economic Development (ORED)
Office of Research Regulatory Affairs (ORRA)
Human Subjects Protection Program (HSPP)

2019 SRAI Midwest/Northeast Section Meeting
Chicago Illinois
April 29, 2019

Getting to Know You!

Fun Facts about Rutgers





1766-2016
RUTGERS 250
Revolutionary for 250 Years

Learning Objectives

1. Describe why clinical trials disclosure matters and list resources and tools to assist investigators and organizations in maintaining compliance

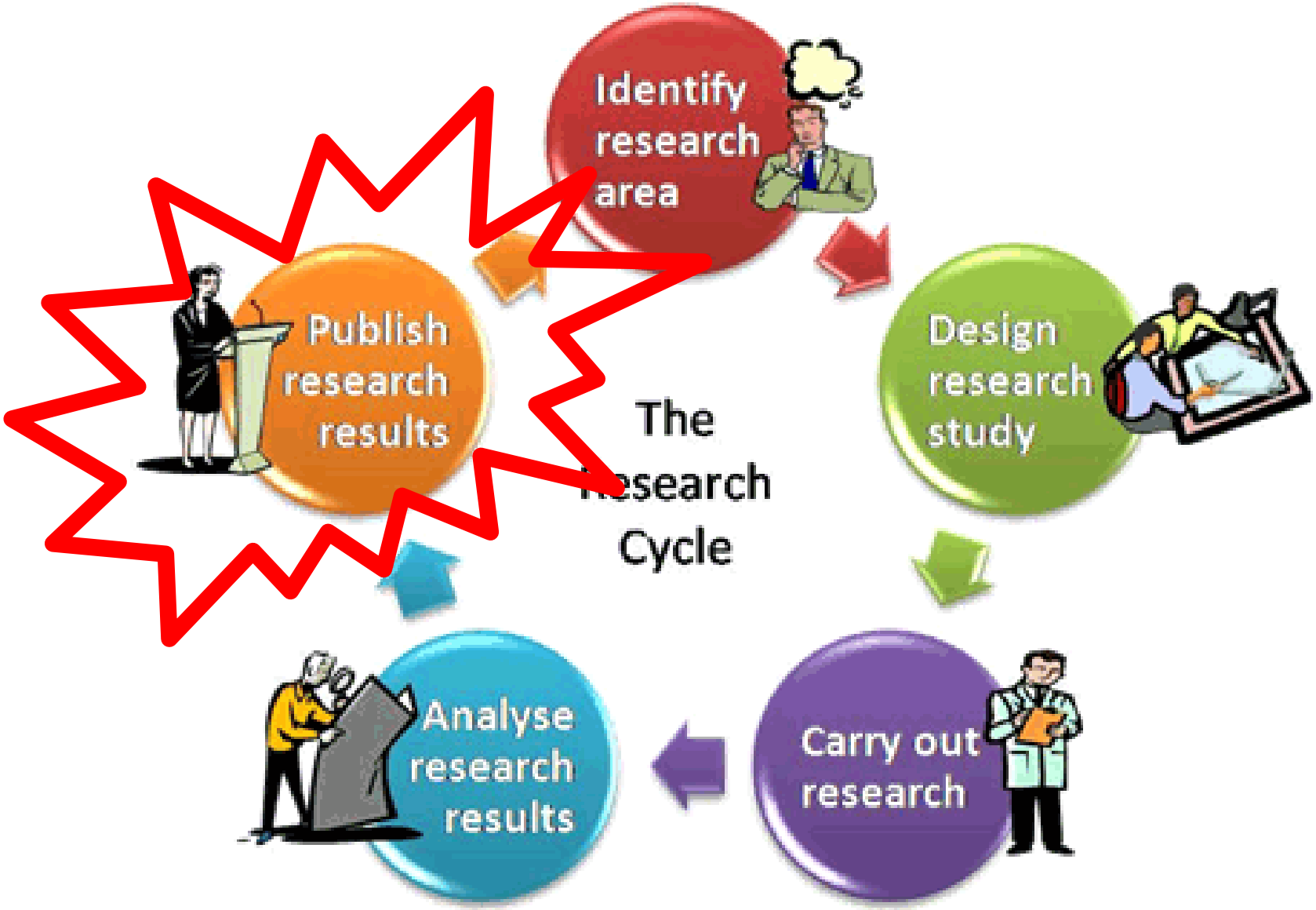
2. Identify key elements to establish a system in your organization to facilitate and monitor clinical trials registration and results reporting

Roadmap

- **Why Do We Care**?
  - ❖ Key issues – 3 pivotal examples
  - ❖ Take-away and Benefits to register
- **What …..**
  - ❖ is ClinicalTrials.gov?
  - ❖ is a “Clinical Trial”?
  - ❖ are the Regulatory Bodies?
- **Who’s Watching?**
- **Reporting Responsibilities**
- **Establish a System in Your Organization**
- **Resources**
  1. NIH
  2. CONSORT (Consolidated Standards of Reporting Trials)
  3. ClinicalTrials.gov website, Protocol Registration System (PRS) email
  4. Clinical Trials Registration and Results Reporting Taskforce

Why Do We Care?

Watch Out!


Identify research area
Design research study
Carry out research
Analyse research results
Publish research results
The Research Cycle

Three Pivotal Cases

- **Paxil**
  - GSK suppressed evidence on harms and lack of efficacy in children

The Washington Post

N.Y. Sues Paxil Maker Over Studies On Children
Negative Data Withheld, Attorney General Says

By Brooke A. Masters
Washington Post Staff Writer
Thursday, June 3, 2004; Page E01

NEW YORK, June 2 -- Drug manufacturer GlaxoSmithKline PLC misled consumers and committed fraud by suppressing clinical studies that raised doubts about the safety and effectiveness of its top-selling antidepressant Paxil when used to treat children and adolescents, New York state Attorney General Eliot L. Spitzer alleged in a civil lawsuit filed Wednesday.

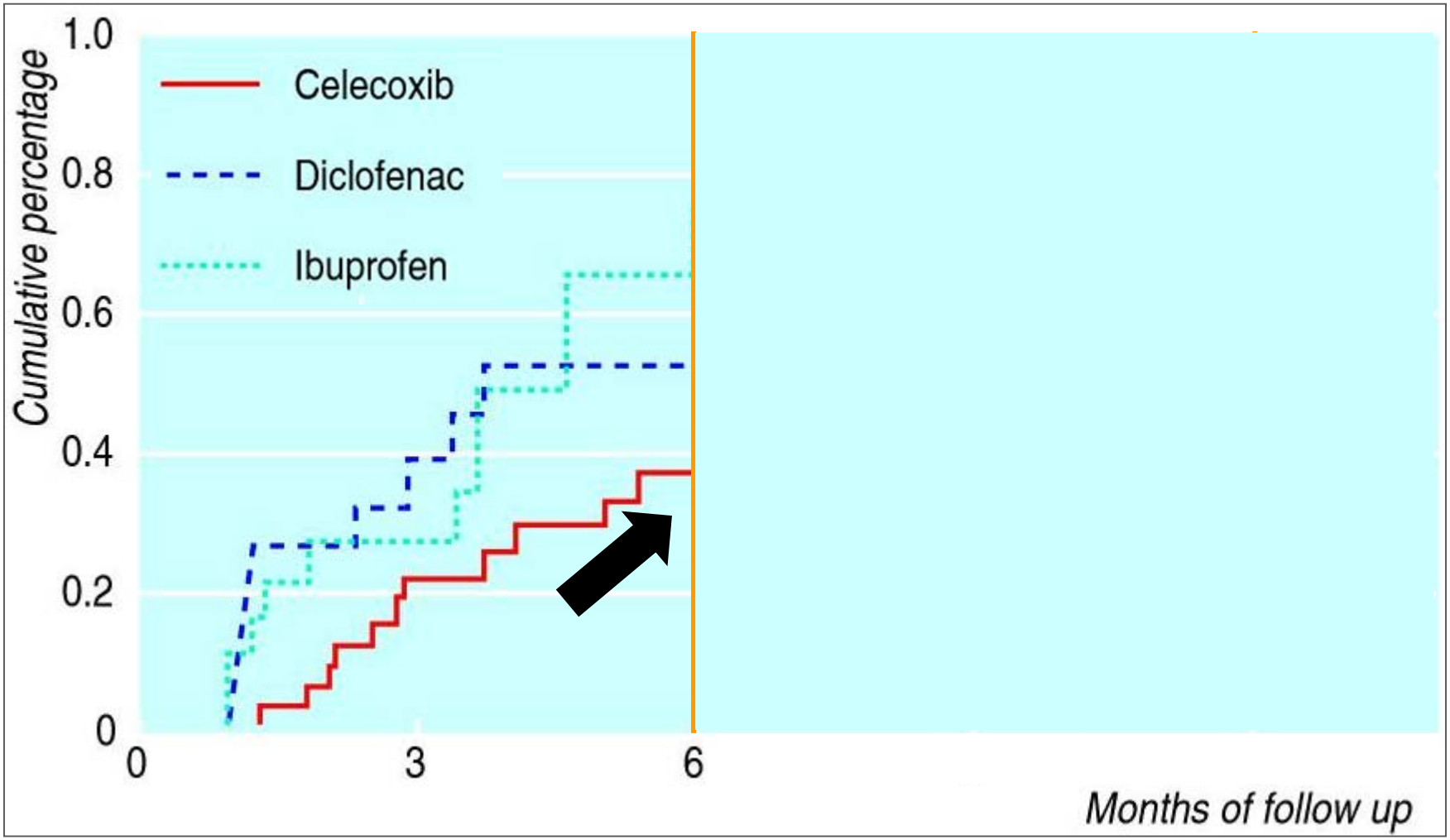
- **Vioxx**
  - Merck failed to report heart attacks


The Washington Times FINAL
FRIDAY, OCTOBER 1, 2004 25 cents
Merck recalls Vioxx
Heart risk found in arthritis drug
PAINFUL
MERCK

- **Celebrex**
  - Pfizer reported misleading results

Celebrex Controversy and Safety Risks

Kaplan-Meier estimates for ulcer complications according to traditional definition. Results are truncated after 12 months, no ulcer complications occurred after this period. (Adapted from Lu 2001.)



Jüni P, Rutjes AW, Dieppe PA. *BMJ*. 2002 Jun 1;324(7349):1287-8.

Take Away

It is scientifically and ethically imperative for researchers to understand that clinical trial registration and results reporting is a key commitment to our research participants.

We all need the results of clinical trials to advance knowledge and inform our medical decisions.

Benefits to Register & Report Results

- **Human Subject Protections**
  - Allows potential participants to find studies
  - Assists ethical review boards and others to determine appropriateness of studies being reviewed (e.g., harms, benefits, redundancy)
  - Promotes fulfillment of ethical responsibility to human volunteers – research contributes to medical knowledge
- **Research Integrity**
  - Facilitates tracking of protocol changes
  - Mitigates information bias (e.g. non publication)
  - Increases transparency of research enterprise
- **Evidence Based Medicine**
  - Facilitates tracking of studies and outcome measures
  - Allows for more complete identification of relevant studies
  - Provides data to support evidence-based medicine"
- **Allocation of Resources**
  - Promotes more efficient allocation of resources

All Contribute to Increased Public Trust in Clinical Research

WHAT ….

…. is ClinicalTrials.gov?

…. is a Clinical Trial?

…. are the Regulatory Bodies?

First Things First: ClinicalTrials.gov

- There are two different systems:
  - ❑ Public site: https://www.clinicaltrials.gov/
  - ❑ User site: Protocol Registration and Results System (PRS) https://register.clinicaltrials.gov/

- There are two basic functions of ClinicalTrials.gov:
  - ❑ Registration (creating and updating the record)
  - ❑ Results Reporting (to be completed within 12 months of “Primary Completion”)

Definition of "Clinical Trial"

Applicable Clinical Trial (ACT): Clinical trial include **interventional** studies (with one or more arms) of FDA-regulated drugs, biological products, or devices.

Clinical Trial (NIH): 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.

Clinical Trial (ICMJE): A research project that prospectively assigns human participants or groups of humans to one or more health-related **interventions** to evaluate the effects on health outcomes.

Determination of NIH "Clinical Trial"

How can researchers determine whether a proposed study is a clinical trial?

- The following questions should be used to determine whether a study meets the NIH clinical trial definition:
  - ❑ Does the study involve human participants?
  - ❑ Are the participants prospectively assigned to an intervention?
  - ❑ Is the study designed to evaluate the effect of the intervention on the participants?
  - ❑ Is the effect being evaluated a health-related biomedical or behavioral outcome?
- If the answers are all "yes," the study is a clinical trial.
- If any answers are "no," the study is not a clinical trial

FAQ: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5220
Case studies: https://grants.nih.gov/policy/clinical-trials/case-studies.htm

Milestones on Transparency

Year	Entity	Event
1997	Congress	*The 1st U.S. law to require trial registration (FDAMA)*
2000	NIH	*Launch ClinicalTrials.gov website*
2005	ICMJE	*Requires registration prior to enrollment*
2006	WHO	*All clinical trials should be registered*
2007	CMS	*PI must enroll qualifying clinical trials in ClinicalTrials.gov*
2007	Congress	*Expanded registration, results reporting and civil penalties (FDAAA)*
2008	NIH	*Release results database in ClinicalTrials.gov*
2013	WMA	*Declaration of Helsinki requires registration & results reporting*
2015	CMS	*Mandatory reporting of clinical trial number on claims*
2016	FDA/NIH	*Final Rule and Companion Policy (effective January 18, 2017)*
2017	FDA	*Final Rule compliance date (April 18, 2017)*
2017	WHO	*Signatories of international agencies to require registration and results reporting (May 18, 2017)*

RUTGERS Selected Trial Registration Laws & Policies

Name	Type	Intervention Type	Registration Policy Scope
FDAAA 801	U.S. Federal Law (2007)	Drugs, biologics, and devices	Controlled clinical investigations of a FDA-regulated drug, biologic, or device, except Phase 1 or small feasibility studies
WMA 2013 Declaration of Helsinki	International policy, adopted by the WMA (1964, 2013)	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." (Para 35)
Clinical Trials Directive 2001/20/EC, Article 11	European Union directive (2001)	Drugs and biologics	Phase 2–4 adult trials and Phase 1–4 pediatric trials
WHO Int'l Clinical Trials Registry Platform	International policy initiated by WHO (2006)	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	"The registration of all interventional trials is a scientific, ethical and moral responsibility."
ICMJE Policy	Publication policy by ICMJE (2004)	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	All interventional studies, including Phase 1 studies; defines criteria for "acceptable registries"

RUTGERS US Clinical Trials Reporting Requirements

Reporting Requirement	ICMJE Policy	FDAAA Final Rule (issued in 9/2016)	Final NIH Policy (issued in 9/2016)
Scope	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All (e.g., including behavioral intervention)
Funding Source	All	All	NIH
Enforcement	**Refusal to publish**	**Criminal proceedings and civil penalties (up to $11,805* ~~$11,569*~~/ day); Loss of HHS funding**	**Loss of NIH funding**
Effective	2005	**January 18, 2017**	**January 18, 2017**

International Committee of Medical Journal Editors (ICMJE)
http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
https://www.federalregister.gov/documents/2018/10/11/2018-22005/annual-civil-monetary-penalties-inflation-adjustment

Requirements for Registration

- **FDAAA**: The Principal Investigator must register and input required clinical trial information through the Protocol Registration System (PRS) at the ClinicalTrials.gov website ***no later than 21 days after enrollment of the first participant*** (https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa).

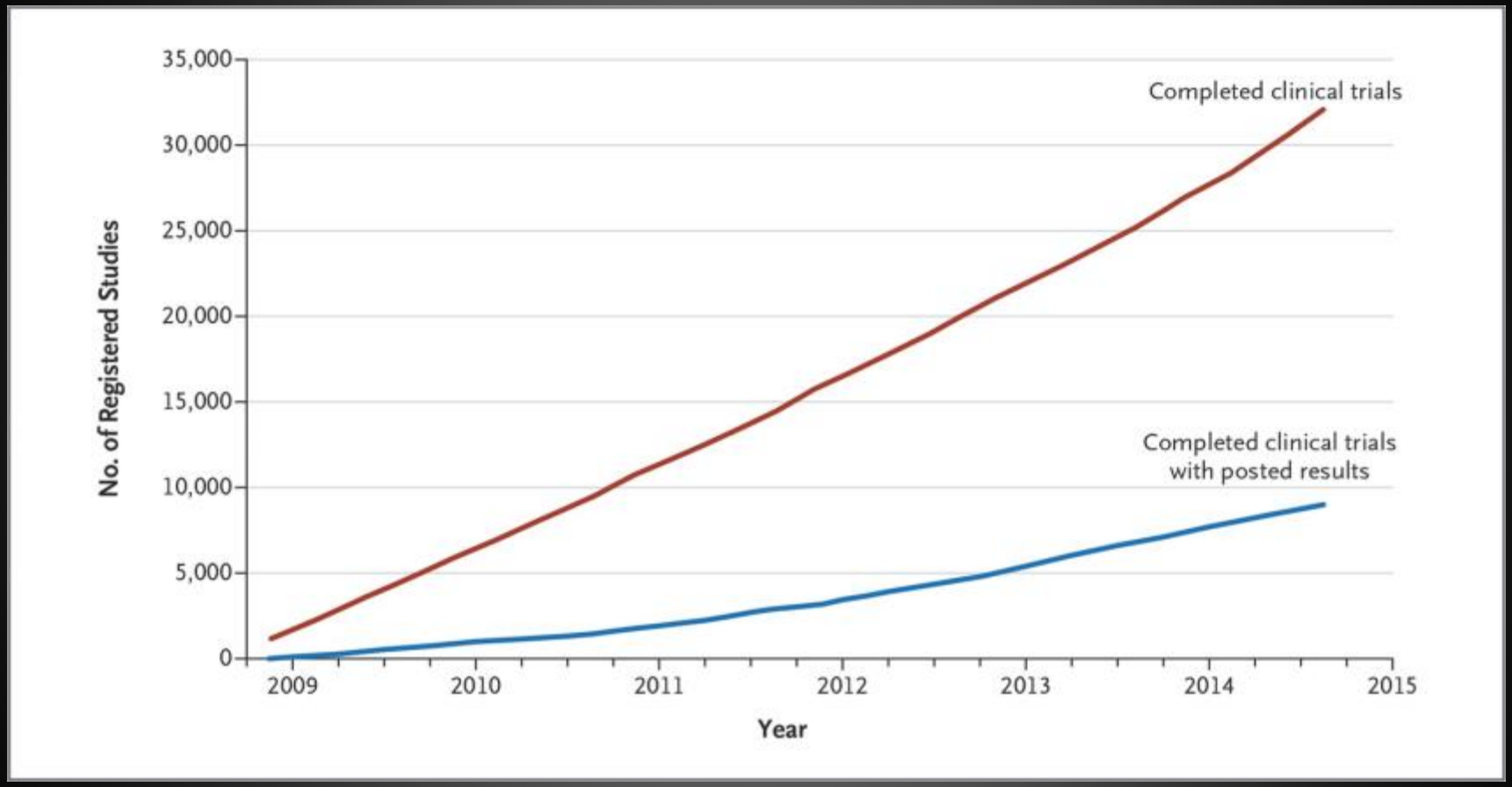
- **NIH**: The Principal Investigator must register and input required clinical trial information at the ClinicalTrials.gov website ***no later than 21 days after enrollment of the first participant*** (https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information).

- **CMS**: The Principal Investigator must register and input required clinical trial information and obtain an NCT# at the ClinicalTrials.gov website ***before submitting claims for such services to CMS***.

- **ICMJE**: The Principal Investigator must register with an ICMJE qualified publicly-accessible registry ***at or before the first patient is enrolled in the study*** as a condition for publication in a participating journal (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration).

Who's Watching?

Cumulative Number of Registered Clinical Trials with at Least One U.S. Site from October 2008 to September 2014



Zarin DA et al. N Engl J Med 2015;372:174-180.

The NEW ENGLAND JOURNAL of MEDICINE

STAT article: Faced with public pressure, research institutions step up reporting of clinical trial results

January 9, 2018

https://www.statnews.com/2018/01/09/clinical-trials-reporting-nih/

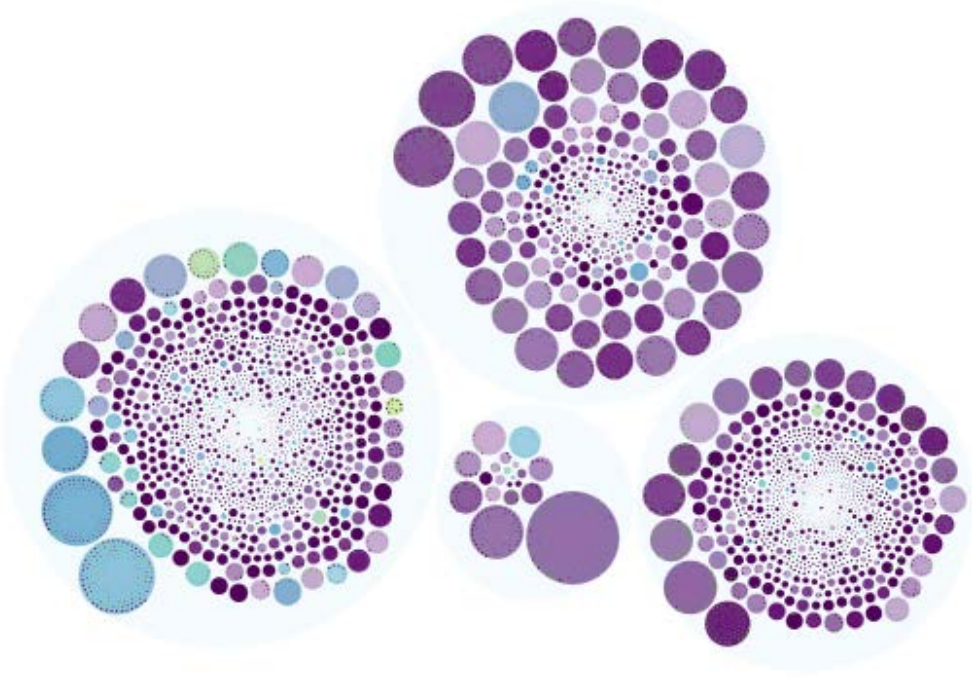
In this visualization, you can explore 12,821 clinical trials that failed to report required results to ClinicalTrials.gov or reported them after the legal deadline, as of Sept. 11, 2017. Reporting violations also were recorded as of Sept. 11, 2015. The violations are grouped by the parties responsible for reporting trial results (the larger the circle, the more violations), and by category of research organization. Click or tap on any of the circles to zoom in or out. Click or tap on the small circles, which represent individual clinical trials, to open the related ClinicalTrials.gov page in a new window. Use the search box to find a particular responsible party.

Clinical trial legend:

- Results missing in 2015 and 2017
- Results missing in 2015; posted late as of 2017
- Results not required in 2015; missing in 2017
- Results not required in 2015; posted late as of 2017
- Results posted late before Sept. 11, 2015

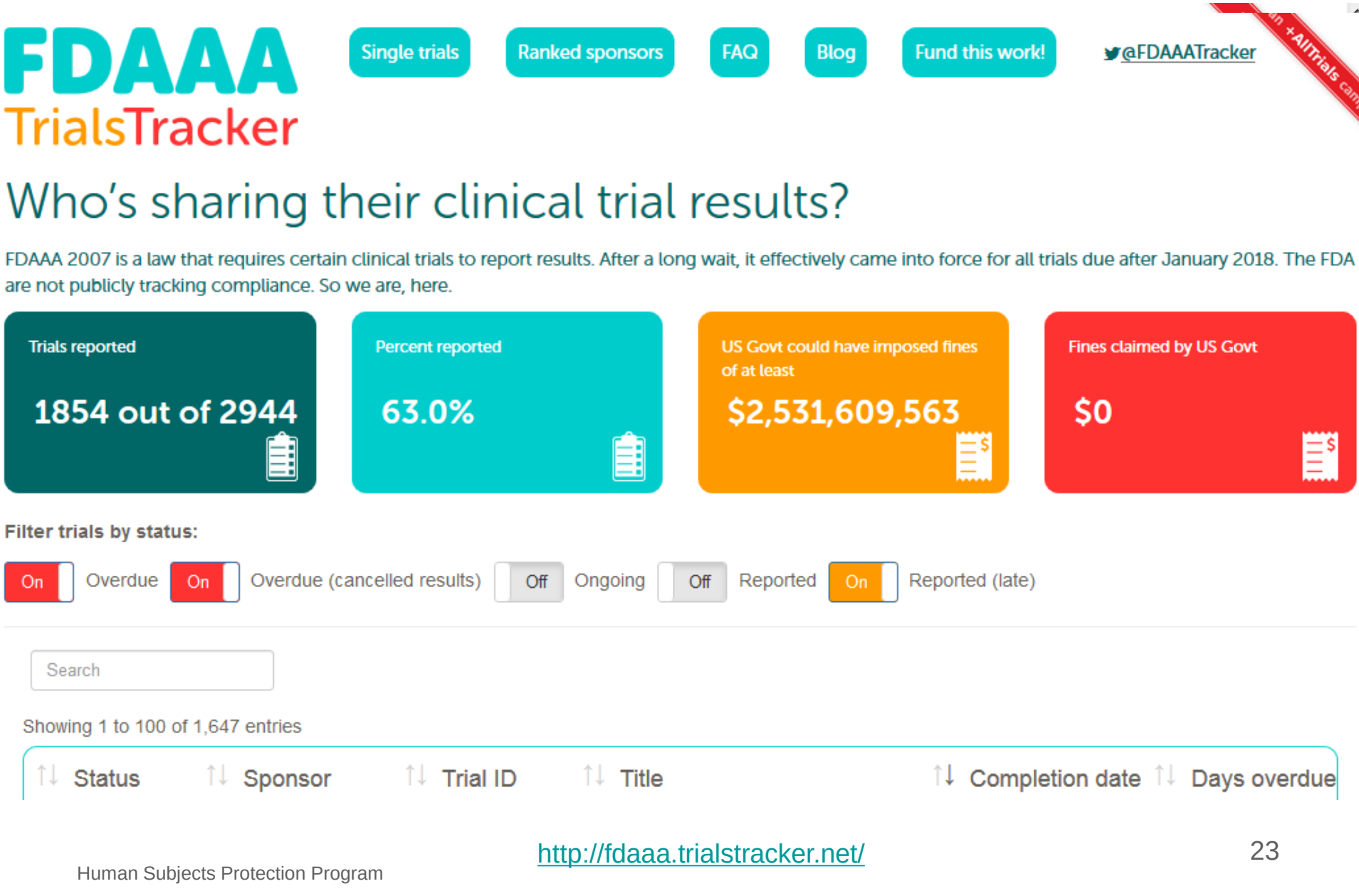
Percentage of each responsible party's clinical trials that had results reported late or not at all.

0% 20% 40% 60% 80% 100%



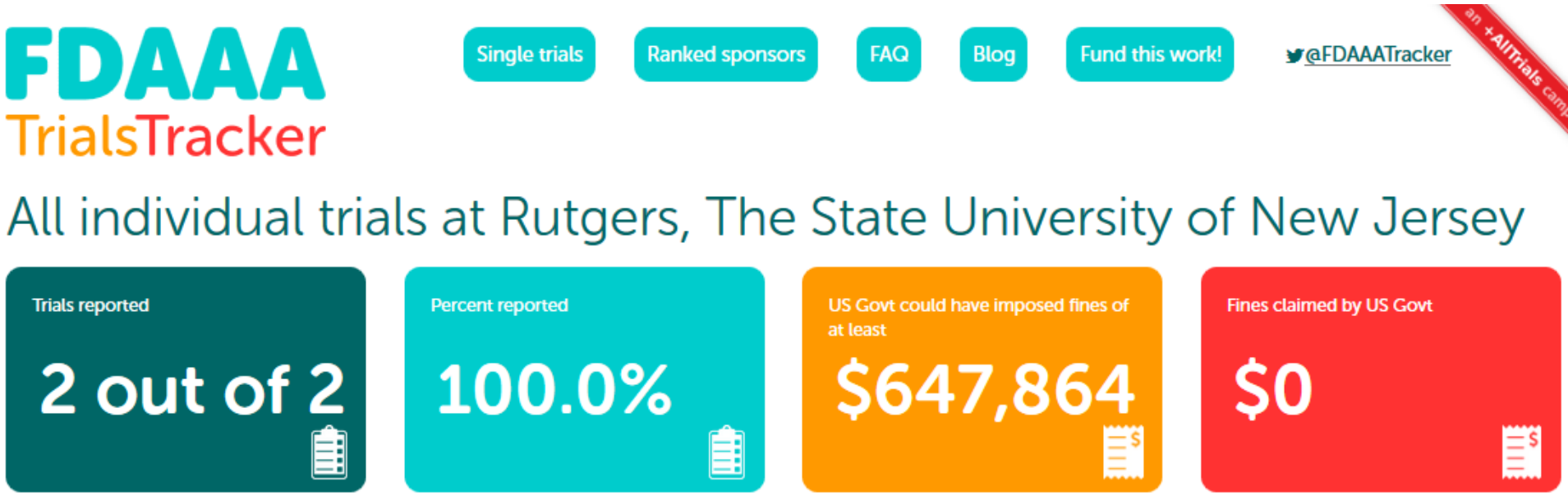
https://www.statnews.com/2018/01/09/clinical-trials-reporting-nih/

AllTrials FDAAA Trials Tracker



http://fdaaa.trialstracker.net/

How's Rutgers Doing on TrialsTracker?



Status	Trial ID	Title	Completion date	Days overdue
reported-late	NCT01753999	Obstructive Sleep Apnea in WTC Responders: Role of Nasal Pathology [pACT]	2017-03-31	86
reported	NCT02632838	Utilizing a Mobile Health (mHealth) Application to Improve Hypertension Monitoring and Self-management in an Underserved Community: A Pilot Study [pACT]	2017-09-30	

nature

NEWS · 26 MARCH 2019

CORRECTION 27 MARCH 2019

Top US institutes still aren't reporting clinical-trial results on time

US law requires researchers to post study findings on a public registry within a year of completion — or face heavy fines.

Nic Fleming

Many leading US universities are breaking the law by failing to make public the results of their clinical trials.

A report published on 25 March found that 25 of the 40 universities that sponsor the most trials in the United States did not post study results on a public, government

RELATED ARTICLES

US toughens rules for clinic transparency

European clinical

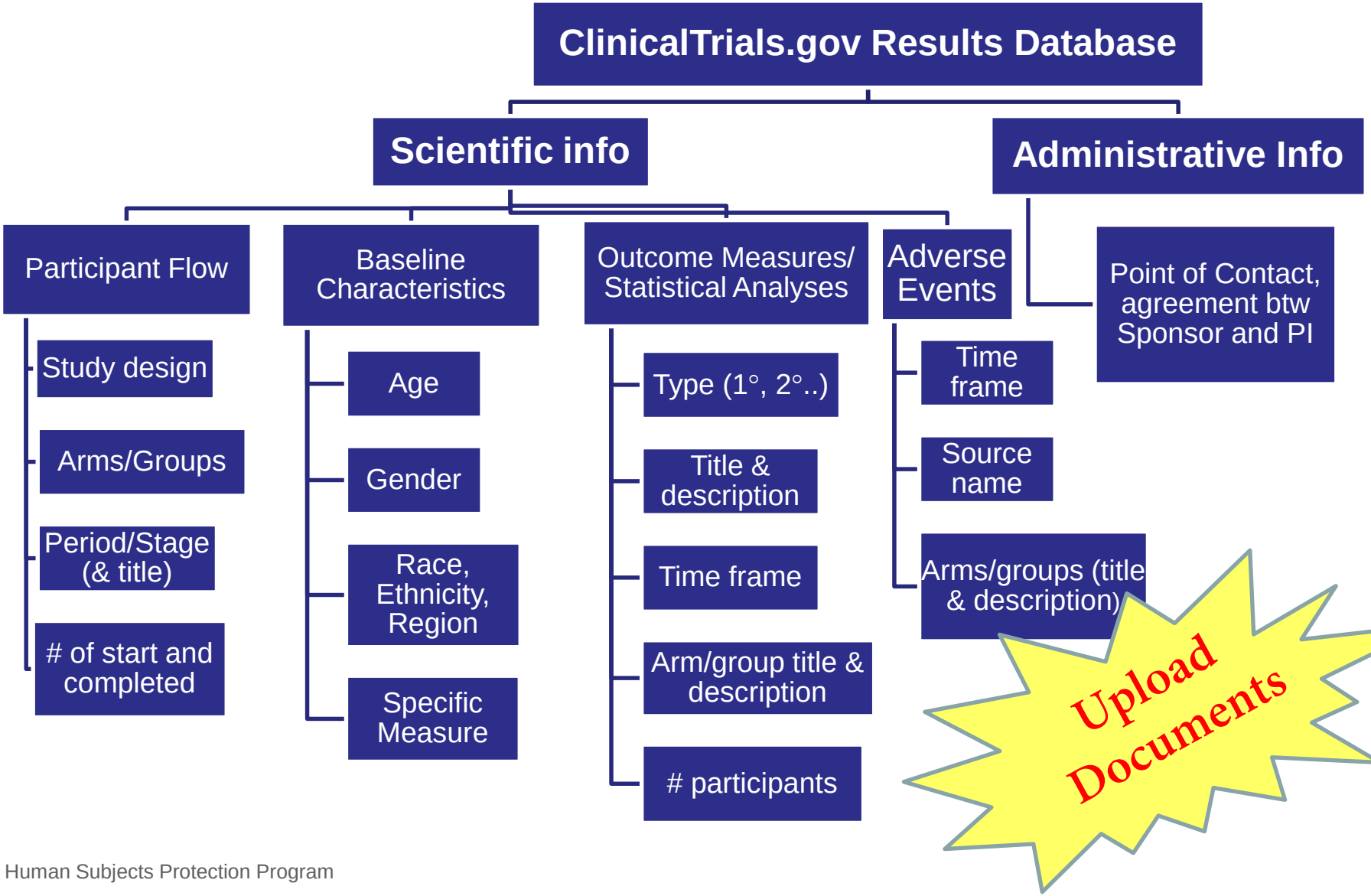
https://www.transparimed.org/single-post/2019/03/25/New-report-25-leading-US-universities-violate-key-medical-transparency-law
https://www.nature.com/articles/d41586-019-00994-1#correction-0

Reporting Responsibilities

Key Concepts

- Responsible Party (i.e. PI per RU policy) must submit scientific and administrative information
- PI and statistician(s) are strongly encouraged to be involved
- Summarize results information in tabular format
- Conceptually similar to prepare for journal manuscript
- The intended audience is “readers of the medical literature.”
- The Basic Results Database requires the reporting of what was done; it does not require a change in study design or study procedures;
- Quality Assurance is designed to ensure that results are complete and meaningful; it does not ensure that studies are valid, useful, or interesting!

Overview - Results Database



Summary of Updated Federal Requirements

Final Rule

- Requires registration & results submission for “applicable clinical trials” (ACTs)
- Requires submission of **Protocol** and **Statistical Analysis Plan (SAP)** at time of results information submission
- Expands scope of results reporting requirements to include trials of unapproved products

2018 Common Rule

- Requires posting of an IRB-approved version of the consent form to a federal website/registry, such as ClinicalTrials.gov.

Data Sharing Policies

- NIH Sharing Policies and Related Guidance on NIH Funded Research https://grants.nih.gov/policy/sharing.htm

- ICMJE requirements

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.

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Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank

Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice (OGCP)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health(CDRH)
Office of Regulatory Affairs (ORA)

September 2018

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM607698.pdf

Record Status

In progress → Entry Completed → Approved → Released → PRS Review → Public

1. **In progress** – initial data entry or update ongoing
2. **Entry Completed** – ready for internal review by administrator/investigator
3. **Approved** – record passed internal review
4. **Released** – submitted to ClinicalTrials.gov
5. **PRS Review** – under review by ClinicalTrials.gov
6. **Public** – posted on ClinicalTrials.gov public web site

Compliant Issue
vs
Scientific Issue

Blue = what Investigators need to do

Establish a System in Your Organization

Establish a System in Your Organization

A. Identify a point person to assist investigators
B. Initiate a mechanism to identify clinical trials in your organizations
C. Create a user-friendly website
D. Work with Research Administration to create policy and procedures for registration and results reporting. Update as necessary.
E. Provide active outreach to investigators and staff, offering education and timely information
F. Act as a liaison between investigators and ClinicalTrials.gov Team in NIH

A. Identify a Point Person to Assist Investigators in Your Organization

1. **Who does this position(s) fall under at your institution**?
2. **How are you funding this position(s)?**
3. Consider the following to explore options on the ClinicalTrials.gov Protocol Registration System (PRS) Administrator support :
   - Full Time Employee (FTE)
   - Funding Source
   - Chain of Command

Rationale and Advantages of Having PRS Administrator Role in the Human Subjects Protection Program (HSPP)

1. Clinical trials registration and results reporting is a Human Subjects Protection (HSP) issue.
2. The position aligns with the Declaration of Helsinki paragraph 35 and 36 (updated October 2013) *"All study results inconclusive, negative or positive be made public"*
3. HSPP has the access to IRB study database which enables internal monitoring and management.
4. HSPP PRS Administrator conducts quality assurance review of protocols newly registered on ClinicalTrials.gov.
5. Ability to monitor non-compliance with Federal Regulations

B. Initiate a Mechanism to Identify Clinical Trials and Facilitate Registration

Mechanisms in place at Rutgers Institutional Review Board

- eIRB application questions on investigators to self report
- IRB changed the protocol templates to distinguish "interventional studies" and "non-interventional studies"
- Forms of initial application and renewal contain pertinent questions

Mechanisms in place at Human Subjects Protection Program

- PRS Administrator generates a monthly report from eIRB of newly IRB-approved studies to capture interventional studies required to register on ClinicalTrials.gov

Rutgers eIRB Questions that prompts the investigator to register the trial on ClinicalTrials.gov

- **Is this a Research Study which prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes?**
  Yes / No
- * **Is this a clinical trial** defined as an Interventional trials (drugs, biologics, device), Phase II-IV , device trials for which FDA approval is sought(IND/IDE)?
  Yes / No

If YES:

- You have indicated that this is a Clinical Trial or a research study which prospectively assigns human participants or groups of human participants to one or more health related interventions. This requires ClinicalTrials.gov **registration** per FDA Regulations and/or ICMJE Registration Policy. This study must be registered at ClinicalTrials.gov within **21 days** of enrollment of the first participant.
  Requirements: http://rbhs.rutgers.edu/hsweb/clinicaltrials/requirements.html
  ICMJE Registration Policy: http://rbhs.rutgers.edu/hsweb/clinicaltrials/icmje.html
- **Please select all classifications that apply:** (phase of the study)
- **Identify your ClinicalTrials.gov point person of your study:** (include name and contact information)

C. Create a User-Friendly Website:

- Establish a website of clinical trials registration and results reporting
- Provide information and resources
- Conduct trainings on how to navigate and utilize the website
- Regularly update it

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Home About Us HSPP / IRBs IACUC Export Control Research Integrity Conflict of Interest

- Home (Clinical Trials)
- Investigator Responsibilities
- Policies & Regulations
- Training & Education
- FAQs
- Resources
- Contact Us

Search our site...

Clinical Trials Registration and Results Reporting

Printer-friendly version

Overview

This website is intended to help Rutgers Investigators understand the requirements and responsibilities for clinical trials registration.

Creating An Account and Registering Your Protocol On ClinicalTrials.gov

ClinicalTrials.gov is a public database developed by the National Library of Medicine (NLM) that offers up-to-date information for locating federally and privately supported clinical trials for a wide range of diseases and conditions. Information available on ClinicalTrials.gov includes registration and results reporting information. ClinicalTrials.gov background information can be found on the ClinicalTrials.gov.

Instructions

1. Create an ClinicalTrials.gov Account: View Instructions [PDF]
2. Register Your Study (Enter the PRS Website)

Need Help? Contact Us

Definition of 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. (NIH.gov)

- Does Your Human Subjects Research Study Meet The NIH Definition Of A Clinical Trial? (NIH.gov)

D. Work with Research Administration to Create Policy and Procedures for Registration and Results Reporting. Update as necessary.

Ad hoc committee meet with the Institutional Official to discuss details of policy and procedures, including enforcement for registration and results reporting.

Rutgers Policy

OFFICE OF RESEARCH REGULATORY AFFAIRS POLICY

Policy Name:	**Clinical Trials Registration and Results Reporting**
Approval Authority:	**Institutional Official**
Originally Issued:	**June 1, 2017**
Adopted:	**June 1, 2017**
Amended:	**February 25, 2019**
Amended Approved:	**March 19, 2019**
Responsible Executive:	**Associate Vice President, Office of Research Regulatory Affairs**
Responsible Office:	**Office of Research Regulatory Affairs**
Contact:	**Human Subjects Protection Program** **https://orra.rutgers.edu/hspp** **(973) 972-1149**

1. **Policy Statement**
   The University requires registration and results reporting of certain clinical trials (as defined in Section 5 below) at ClinicalTrials.gov, a publicly-accessible registry, to promote responsible dissemination of information about clinical trials to the public, ensure compliance with pertinent Federal and State law and funding agency requirements, and to meet professional publication standards.

2. **Reason for the Policy**
   Title VIII of the Food and Drug Administration Amendment Act of 2007 (**FDAAA**) established legal requirements for sponsors and designated principal investigators responsible for certain clinical trials to register and report results information to ClinicalTrials.gov. To comply with FDAAA, the National Institutes of Health (**NIH**) and the Center for Medicare and Medicaid Services (**CMS**) obliges grantees to follow registration and reporting requirements to qualify for funding. Further, the International Committee of Medical Journal Editors (**ICMJE**) established similar standards investigators must follow if they wish to publish in participating journals. This policy is intended to provide an organizational framework around and support to University investigators responsible for complying with regulation, grantor requirements and/or publication standards regarding registration and reporting.

3. **Who Should Read this Policy**
   This policy applies to all faculty, staff and other employees, students, or other individuals conducting clinical trials requiring registration and results reporting on University premises, using University property or facilities, and University Institutional Review Board (IRB) authorization.

https://orra.rutgers.edu/sites/orra.rutgers.edu/files/HSPP/Auditors/ORRA%20Policy%20on%20Clinical%20Trials%20Registration%20and%20Results%20Reporting_FINAL_July%207%202017.pdf

E. Provide Active Outreach and Education

Customized, extensive opportunities for training to meet individual and/or group needs are offered:

- **Rollout Sessions** were given at all campuses.
- **All IRB Executive Committees** received an introductory session, and continuous updates.
- **Department or Group Meetings** are encouraged to include a presentation of ClinicalTrials.gov on the agenda.
- **Personalized Tutoring/Meetings** are conducted with individual faculty and their staff.
- **Individual Phone Consultations** are available upon request.
- **IRB Open House** had a ClinicalTrials.gov information table, next to our ClinicalTrials.gov poster.

ICMJE requirements for result reporting if investigators intend to publish

- ICMJE policy requires public, prospective registration in an acceptable public registry or in the World Health Organization (WHO) International Clinical Trials Portal.
- ICMJE requires Principal Investigators to adhere to the registration guidelines of the chosen registry.

The HSPP ……

- recommends ClinicalTrials.gov tools for data collection in preparation for manuscripts.
- explores investigators intent to publish.
- familiarizes investigators with the ICMJE registration timeline for enrolling participants.
- provides guidance for investigators to meet ICMJE reporting requirements.

F. PRS Administrator's Expanded Role in Maintaining Compliance

- Participate in ClinicalTrials.gov Taskforce, a nation-wide group joined by institutional PRS administrators. Activities include monthly conference calls and various subcommittees to collaborate on projects and issues.
- Open communication with ClinicalTrials.gov PRS Team at National Institutes of Health. Act as a liaison between investigators and the ClincialTrials.gov PRS Reviewers.
- Identify and share best practices with other institutions
- Develop solutions and tools for regulatory support
- Respond to requested consultations with from around the country
- Expand institutional knowledge with the Taskforce update on a regular basis.

RESULTS

1. Developed and implemented an **Institutional Policy** and Procedure approved by the Institutional Official and Vice President of Research
2. Initiated collaboration with other departments to **develop in-house procedures** for the institution to maintain in compliance (e.g. investigators separation procedure)
3. **Increased** research faculty **awareness** on registration and result reporting
4. Run monthly reports in ClinicalTrials.gov to **check for compliance with institutional policy**
5. Human Subject Protection Analysts now review and include a section on the obligation and responsibility of clinical trials registration and results reporting when conducting **in-house Quality Assurance, Routine and For-cause Reviews**.

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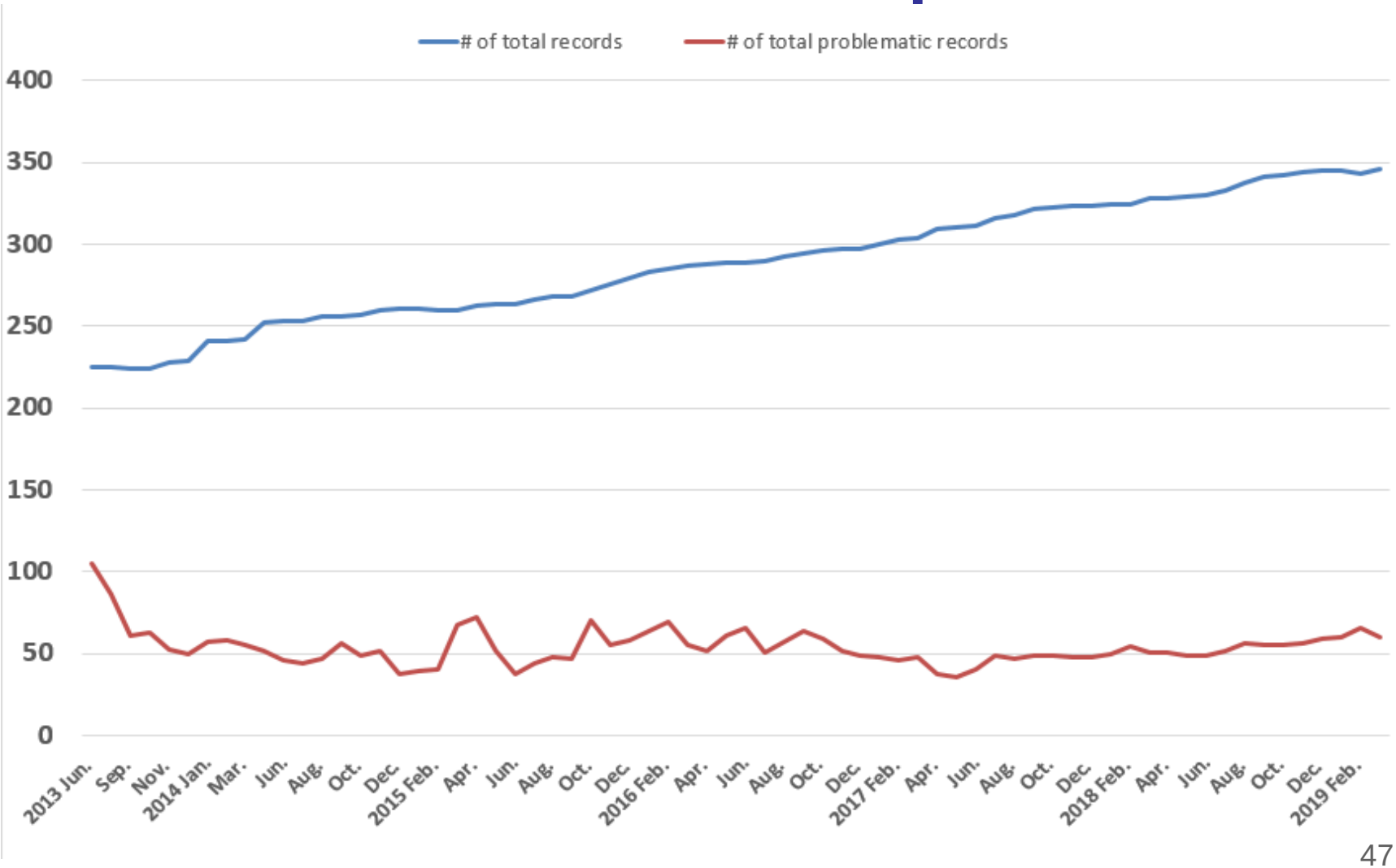
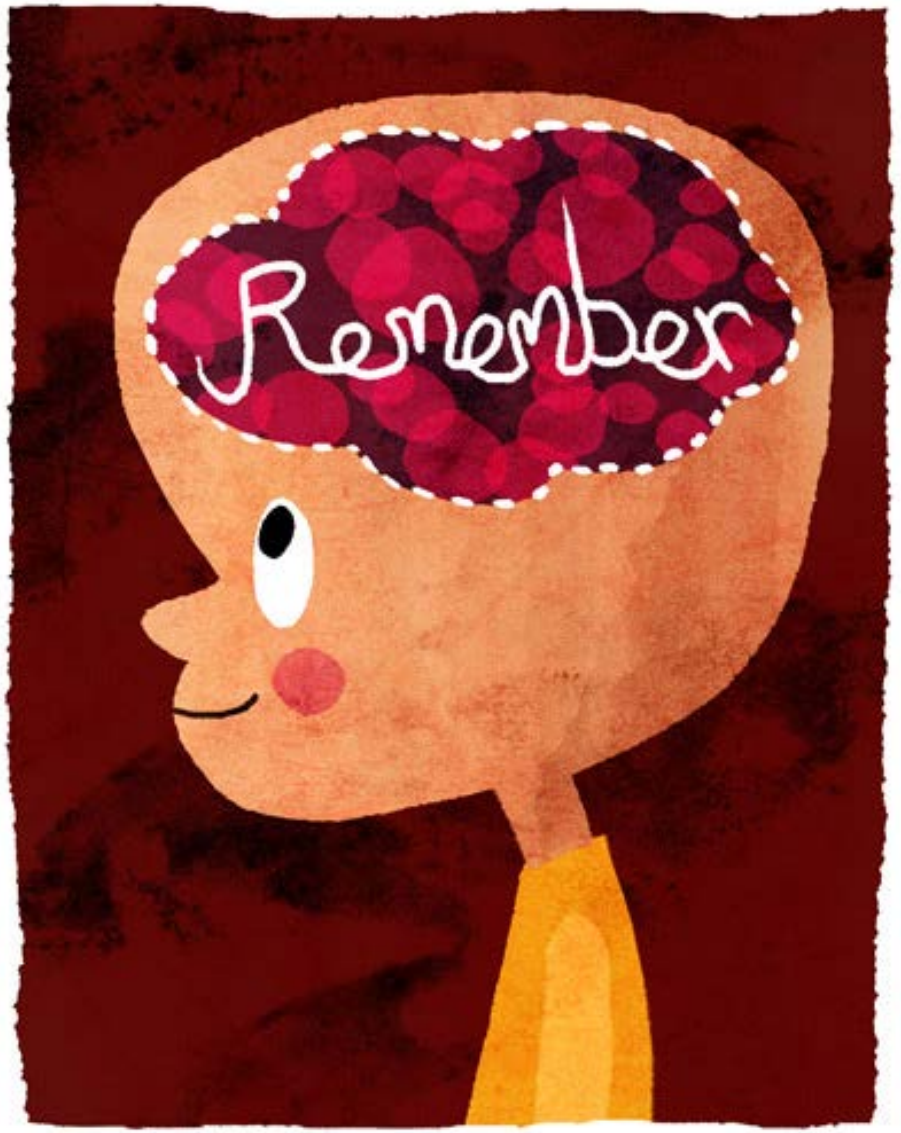
Total Numbers of Registered ClinicalTrials.gov Records at RU Jun. 2013 – Apr. 2019



Our ultimate goal is to be a resource to our research faculty, so that they know that they can always come back for support at any given time.



CONCLUSION

- Besides a major increase in registration, data reporting, and a reduction in problem items, investigators now view HSPP as a valuable resource not merely a compliance overseer.

- *"Results reporting should not be considered a burden. Reporting results is an essential part of the scientific process; it is an integral component of the scientific method." (Michael S. Lauer, MD, Extramural Research, NIH)*

Resources

1. NIH
2. CONSORT
3. ClinialTrials.gov official website, and its Protocol Registration System (PRS) Website & PRS email
4. Clinical Trials Registration and Results Reporting Taskforce (CTRRT)

National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

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Home » Policy & Compliance » Clinical Trials » NIH Clinical Trial Definition - Frequently Asked Questions

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight
- **Select Policy Topics**
  - Animal Welfare
  - Application Submission Policies
  - Clinical Trial Requirements
    - Clinical Trial Definition
    - Why the Changes
    - Good Clinical Practice
    - Specific Funding Opportunities
    - New Form
    - Single IRB Policy
    - Protocol Template
    - Registration and Reporting
  - NIH Funding Strategies
  - Human Subjects Protection Program

Frequently Asked Questions

NIH Clinical Trial Definition

Public FAQs
NIH Staff FAQs

Initial Posting: August 10, 2017
Last Revised: September 8, 2017

More FAQs on clinical trial-related topics

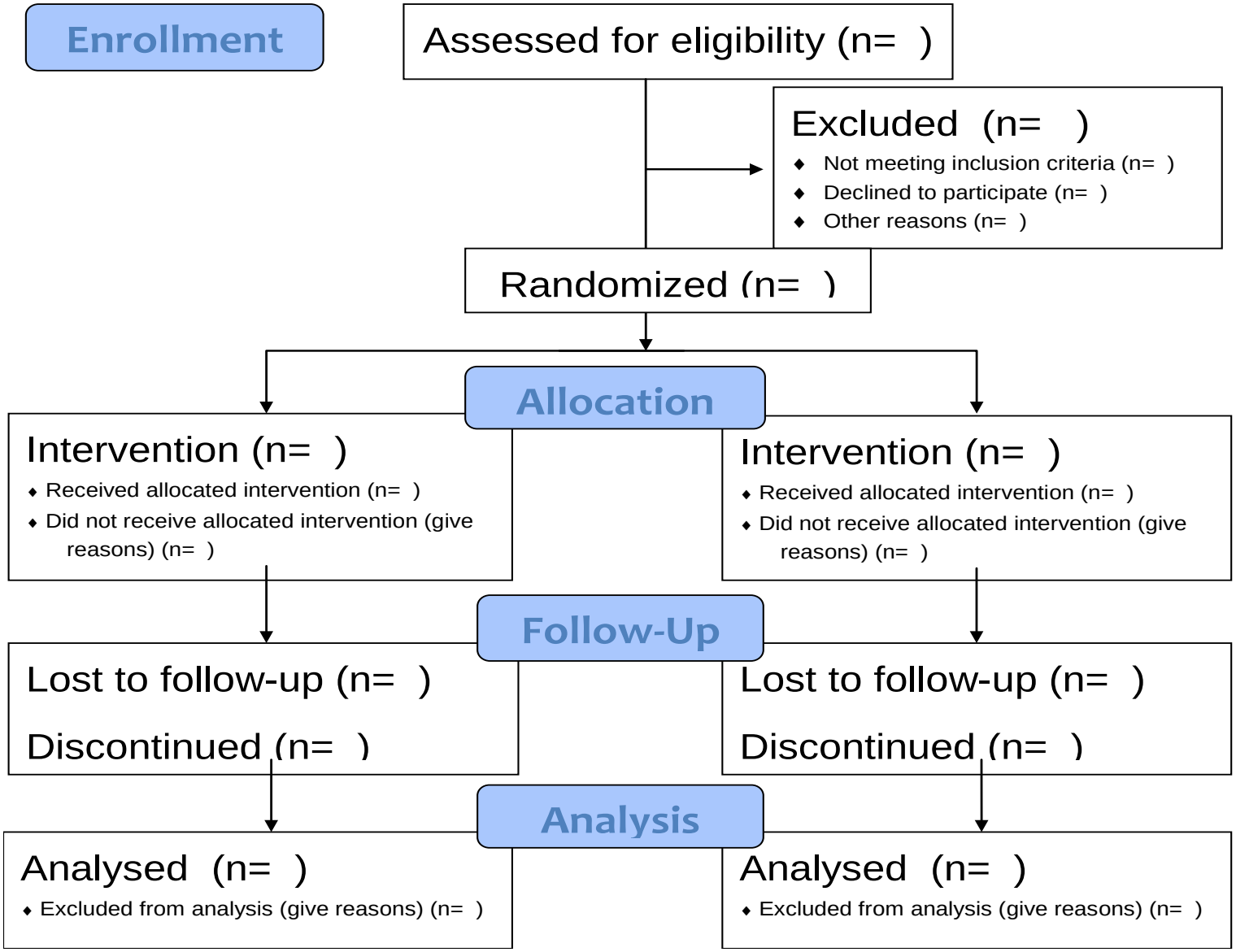
Filter | Refresh

A. QUESTIONS ABOUT THE CLINICAL TRIAL DEFINITION — Expand/Contract

How will NIH educate researchers? NIH will continue to update case studies, FAQs, tools, and resources to clarify guidance around the NIH clinical trial definition. See resources at: https://grants.nih.gov/policy/clinical-trials.htm Additionally, **NIH staff are prepared to help researchers determine whether their studies meet the NIH clinical trial definition.**

https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm

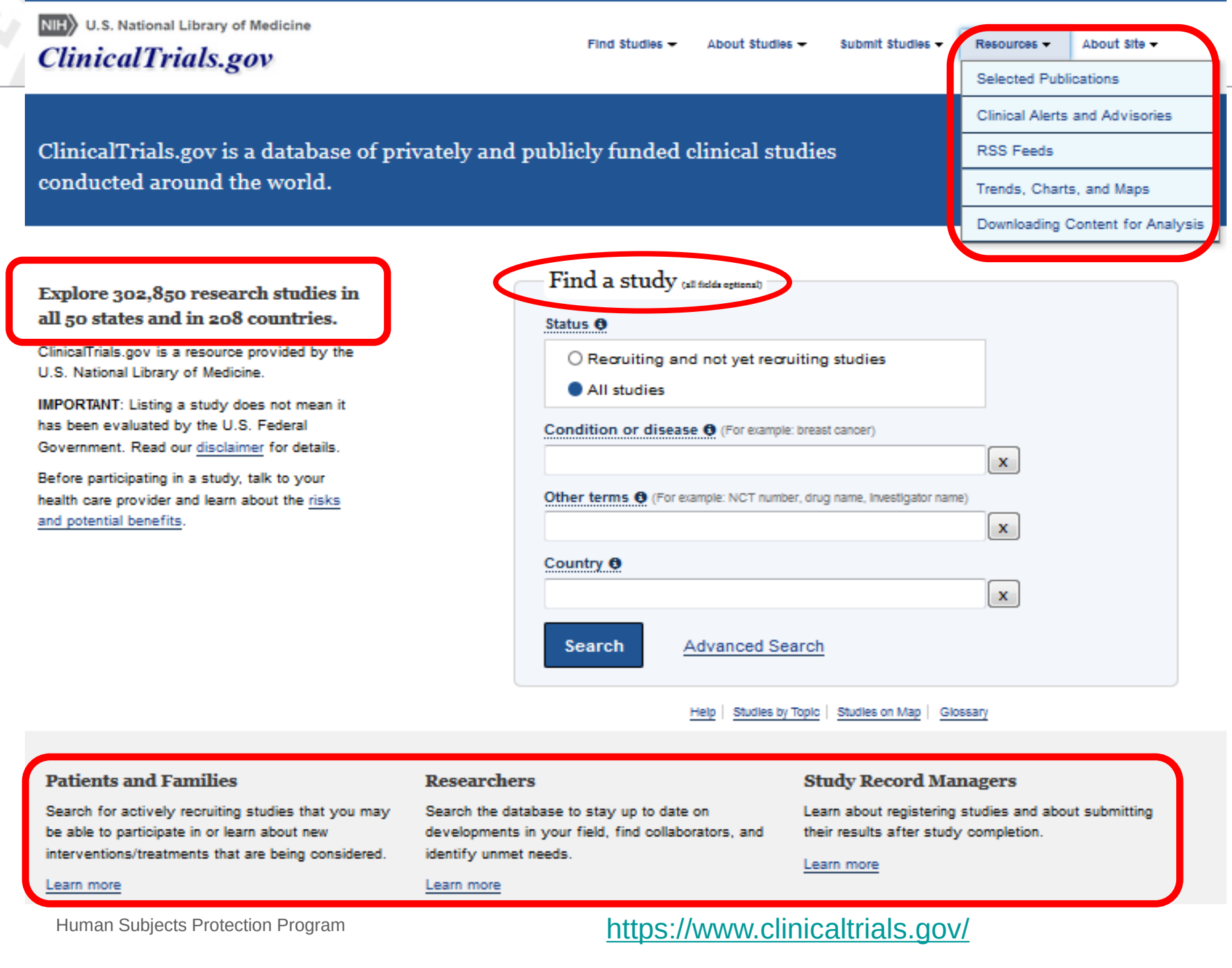
CONSORT 2010 Flow Diagram



CONSORT checklist: Six Sections/Topics, 25 items

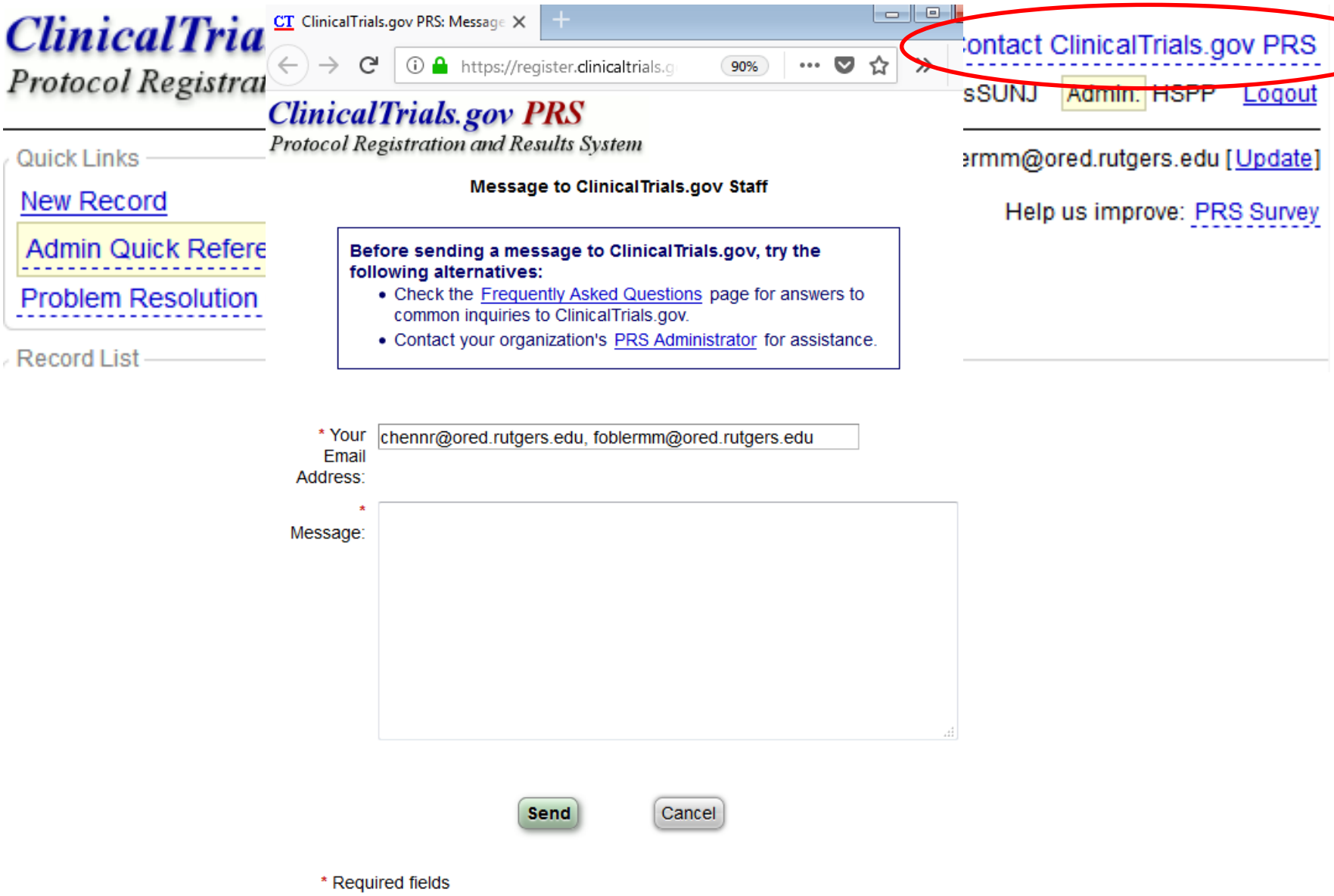
Sections/Topics	Checklist Items
Title and abstract	Trial title; Structured summary of design, methods, results & conclusion
Introduction	Background and objectives
Methods	Design, participants, interventions, outcomes, sample size, randomization, blinding, statistical methods
Results	Participant flow, baseline data, number analyzed, outcomes and estimation, harms, ancillary analyses,
Discussion	Limitations, generalizability, interpretation
Other Information	Registration, protocol, funding

http://www.consort-statement.org/



https://www.clinicaltrials.gov/

Email PRS & Request A Conference Call



Clinical Trials Registration and Results Reporting Taskforce

HOW TO JOIN | CONTACT

HOME ABOUT CALENDAR RESEARCH RESOURCES FAQS

The Clinical Trials Registration and Results Reporting Taskforce is a national consortium of members of academic medical centers, universities, hospitals, and non-profit organizations focused on the implementation of domestic clinical trials registration and results reporting requirements in the ClinicalTrials.gov public repository. The objectives of the group are to identify best practices, develop solutions and tools for regulatory support and investigators, and serve as a communication forum.

How to Join

Interested in joining the Taskforce?

Read more at our Membership webpage!

Next Meeting

Please join us at our next Taskforce meeting on **Thursday, April 18, 2019 from 1-2pm EST.**

Pam Miller (NEJM) will be presenting on *Data Sharing Practices* at our next meeting.

Do you have a topic that you would like to discuss at an upcoming taskforce meeting? Please email Sarah or Tony.

Objectives:

- Identify best practices
- Develop tools for regulatory support and investigators
- Serve as a communication forum

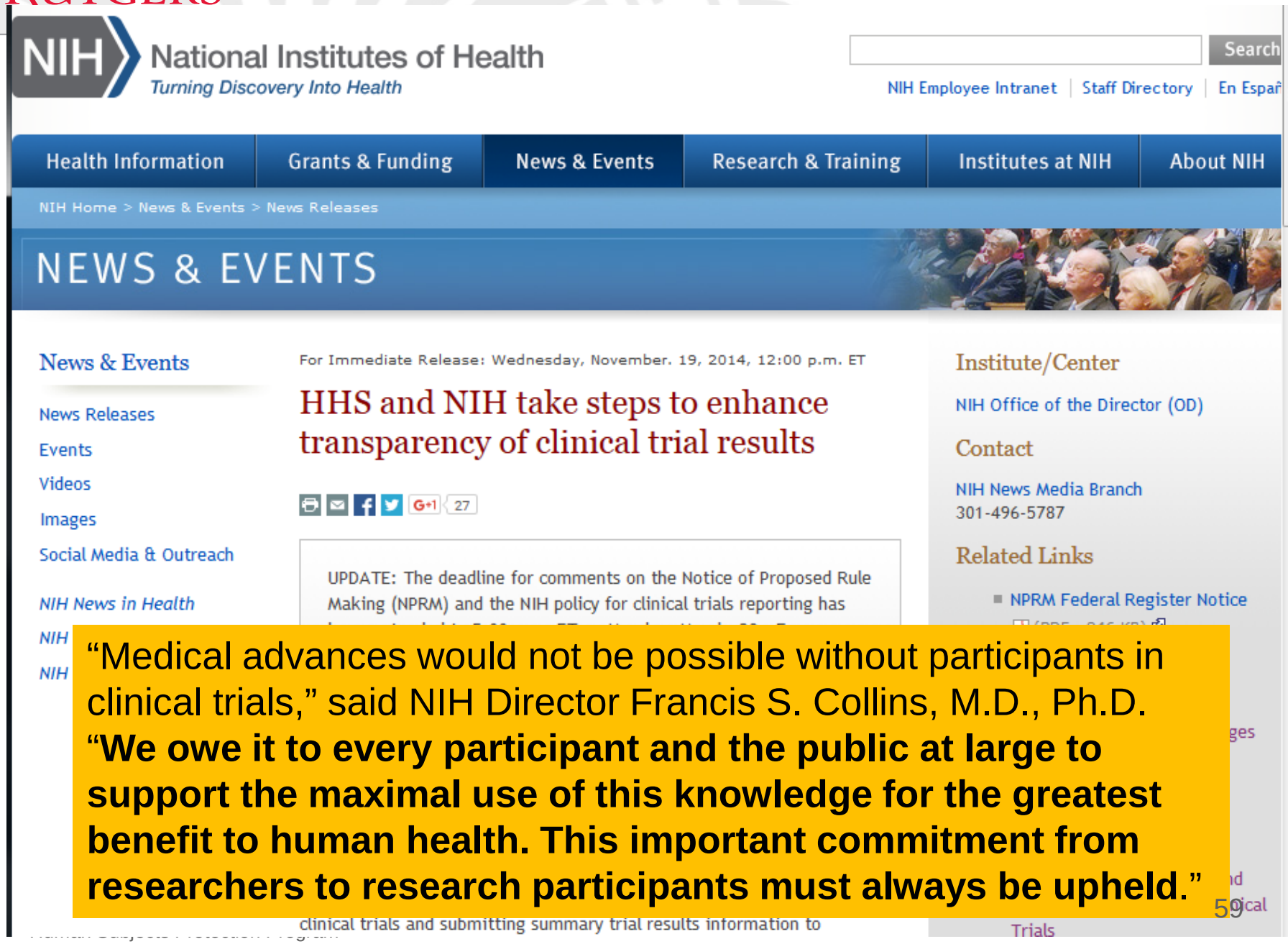
Visit https://ctrrtaskforce.org/membership to join!

Clinical Trials Registration and Results Reporting Taskforce

Monthly Conference call: 3rd Thursday 1 -2 pm EST
Visit https://ctrrtaskforce.org/membership to join!

Examples of our work:

- Template presentation slides (registration & results reporting)
- Template questions to identify Applicable Clinical Trials and trials triggering NIH policy (in eIRB application)
- Administration and oversight benchmark survey
- Guidance: manage relocation of the Responsible Party
- Sample job descriptions
- Manual of considerations for protocol redaction prior to posting
- Forum for feedback to ClinicalTrials.gov staff



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NIH News in Health
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For Immediate Release: Wednesday, November. 19, 2014, 12:00 p.m. ET

HHS and NIH take steps to enhance transparency of clinical trial results

G+1 27

UPDATE: The deadline for comments on the Notice of Proposed Rule Making (NPRM) and the NIH policy for clinical trials reporting has

clinical trials and submitting summary trial results information to

Institute/Center

NIH Office of the Director (OD)

Contact

NIH News Media Branch
301-496-5787

Related Links

- NPRM Federal Register Notice

Trials

"Medical advances would not be possible without participants in clinical trials," said NIH Director Francis S. Collins, M.D., Ph.D. "**We owe it to every participant and the public at large to support the maximal use of this knowledge for the greatest benefit to human health. This important commitment from researchers to research participants must always be upheld.**"

N. Rebecca Chen

Rutgers ClinicalTrials.gov Protocol Registration System (PRS) Administrator

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(973) 972-1149

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