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INSTITUTE *for* CLINICAL & TRANSLATIONAL RESEARCH

Third Thursday: May 18, 2023

Anthony Keyes, MBA, PMP

Program Administrator, Clinical Research Operations

- Research Coordinator Support Service (RCSS)
- Coordinator Apprentice Program (CAP)
- ClinicalTrials.gov Program

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Research Coordinator Support Service (RCSS)

The ICTR Research Coordinator Support Service (RCSS) is a pool of research coordinators that are available for hire on a part-time basis by Johns Hopkins researchers.

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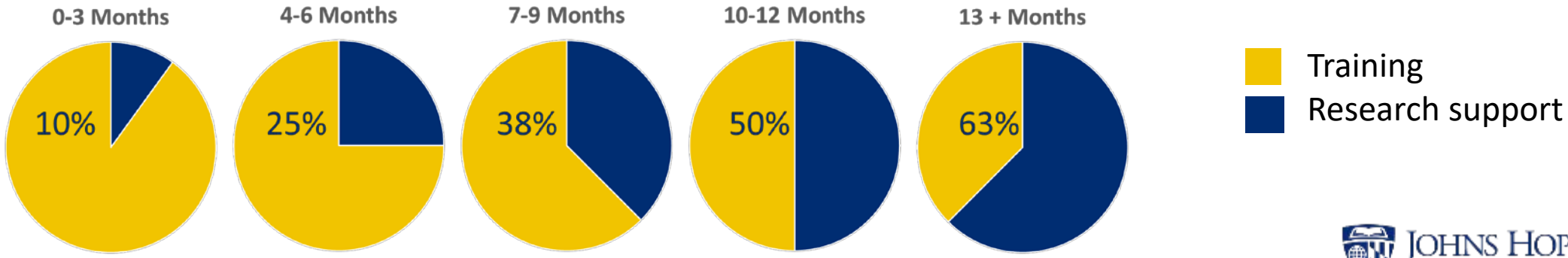
Overview of Program/Core

- SCAMP was established in 2012
  - —Provide coordinator training to trainees with no clinical research training
- RCSS was established in 2014
  - —Provide services to investigators who needed part-time research support
- SCAMP was been re-branded as the Coordinator Apprentice Program (CAP) in November 2020

SCAMP: Study Coordinator Apprenticeship and Mentoring Program
RCSS: Research Coordinator Support Service
CAP: Coordinator Apprentice Program

Rapid Onboarding → Early Assignments

- Tracking tool for completion of required courses and the time/course
  - —Nearly 150 hours of onboarding
- Multiple short-term work assignments of escalating responsibilities
  - —Drugs, devices, behavioral
  - —Sponsored, federally-funded, investigator-initiated
  - —Study status (beginning, middle, end)
  - —Diverse participant populations



(e.g., at 4-6 months, the apprentice will aim for 25%, 10 billable hours per 40 hour work week)

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What's in it for them?

- Opportunity
- Shadowing experienced Coordinators
- 1:1 Mentoring
- Expansive access to training
- Scrubs and a personalized lab coat
- SoCRA membership and test fee
- Free parking

SOCRA
FOR CLINICAL RESEARCH EXCELLENCE

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Current Staff

Role	Number of Staff
Director	1
Sr. Supervisor	1
Sr. Coordinators	1
RCSS Coordinators	5
Year 2 Apprentices	1
Year 1 Apprentices	7
Total	**16**

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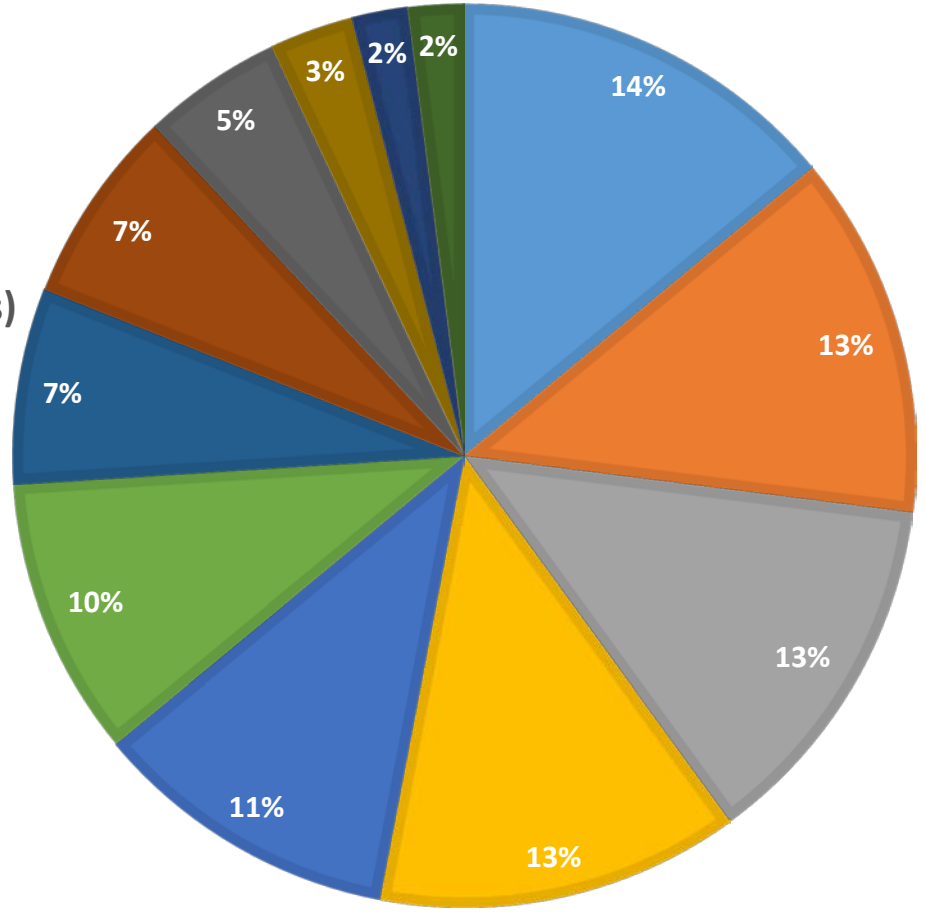
See one, Do one, Teach one

- See one
  - —Shadow experienced coordinators
- Do one
  - —Become an active coordinator
- Teach one
  - —Train a less experienced coordinator

"If you can't explain it simply, you don't understand it well enough"
Einstein

Departments Requests since 2020

- Pulmonary
- Gastroenterology/Internal Medicine/Infectious
- Neuro (Surgery/Onco/Epilepsy)
- Mix (Epid./Geriatrics/Rheumatology/Ortho/Palliative/Immuno./ Onco./others)
- Endocrinology
- Pediatrics (Cardio/Endo/Uro/Nephro/Neuro/GI/Infectious)
- Ophthalmology
- Psychiatry
- Cardiology
- Infectious Disease
- OB/GYN
- Radiology



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How to Connect with us

- https://ictr.johnshopkins.edu/service/study-conduct/rcss/

HOME › SERVICES AND RESOURCES › STUDY CONDUCT › RESEARCH COORDINATOR SUPPORT SERVICE (RCSS)

The ICTR Research Coordinator Support Service (RCSS) is a pool of research coordinators that are available for hire on a part-time basis by Johns Hopkins researchers.

Make a Request

Contact

Tony Keyes
Program Administrator
akeyes1@jhmi.edu

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SCOPE of Work

What coordinator responsibilities do you need support with? (Check all that apply)

- [ ] Feasibility
- [ ] Regulatory support (e.g., IRB applications, binders)
- [ ] Pre-Screening/Screening
- [ ] CRMS/Epic
- [ ] Scheduling/Consenting participants
- [ ] Conducting study visits
- [ ] REDCap
- [ ] Data entry and mangement
- [ ] Study close out
- [ ] Other, please specify

- Connection request
  - —1:1 meeting
    -AND/OR-
  - —REDCap survey
- Assign Coordinator(s)
  - —Based on work assignment
  - —Ongoing Senior level support

SCOPE of Work

What is the weekly work schedule needed? (Check all that apply)

- ☐ Flexible
- ☐ Mondays
- ☐ Tuesdays
- ☐ Wednesdays
- ☐ Thursdays
- ☐ Fridays
- ☐ Weekends (typically not available)
- ☐ Unsure

Study location?

- ☐ East Baltimore, Please specify location(s)
- ☐ Bayview, Please specify location(s)
- ☐ Greenspring, Please specify location(s)
- ☐ Home visits
- ☐ Remote (no study locations)
- ☐ Other, please specify

- Scheduling
  - —Prefer fixed times
  - —Can be flexible
- Location
  - —Multiple available
  - —Usually the study covers parking with vouchers or reimbursement

Program Efficiency

- Work Agreements
  - —REDCap survey interface
  - —Access database that automatically generates Work Agreements
- Monthly Invoicing
  - —Wed-based hours tracking Tool (Clockify)
  - —$60/hr. - Apprentices, Coordinators
  - —$65/hr. - Regulatory Specialists, Sr. Coordinators, Onboarding
  - —Detailed description of tasks done

Impacts

- CAP has trained 51* coordinators since 2012
  - —**81%** (39/48) are still in research
  - —**58%** (28/48) are still at JHU
- Investigators have turned to RCSS
  - —To take on projects they would normally have to turn down
  - —To support research teams that have lost staff members
  - —To supplement their own staffing/knowledge gaps
  - —To grow research portfolios

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*Percentages reported based on 48 we are still in contact with, as 3 are lost to follow-up

Priorities

I. Growing research professionals
   - —Hire the right candidates
   - —Rapid onboarding
   - —Early, study-specific assignments
   - —Ecosystem where Apprentices become mentors

II. Supporting researchers at JHU …and beyond
   - —Assist onboarding their staff
   - —Expand our coordinator onboarding pilot program
   - —Contribute to the national discussion with other CTSAs
   - —Other Universities considering similar programs
   - —Poster presented at ACTS 2023 in DC (04/18/23)

III. Generate revenue to grow the Program

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Research Personnel Onboarding Program

- Who?
  - —RCSS
- What?
  - —For Principal Investigators and Supervisors
  - —Rapidly and efficiently onboard newly hired or less experienced clinical research personnel
  - —Since September 2022, total 21 requests

Completed (Ongoing Support)	Active (Onboarding)	Projected (Coming 2-3 months)	New Requests (Interested)	Cancelled (Fund or project issues or never hired)
8	1	5	3	4

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Research Personnel Onboarding Program

- When?
  - —As early as Day 1
  - —Flexible schedule and prioritized trainings
- Where?
  - —Online courses
  - —Instructor-Led trainings and 1:1 mentoring sessions
- Why?
  - —10 years of experience in training RCSS research coordinators
  - —Strong feedback
  - —Surveys (Coming Soon)

Research Personnel Onboarding Program

- How?
  - —1:1 meeting with PI/Department
    - Trainee's background
    - Studies' need
    - Training Catalogue (Sample on next slide)
  - — Initial meeting with Trainee
    - Trainee's background, soft skills and research path (short term vs long term commitment)
      - Sharpen Skills
      - Advance
      - Motivation (Promotion!)

RCSS Training Catalogue sample

☐ **Required Trainings:** (The box includes the following minimal required courses)

	Training	~Time spent
☐ Johns Hopkins School of Medicine Training (*for New hires*)	☐ New Employee Orientation - JHU	2.5 hrs.
	☐ SOM | Annual Required Training - 2023 ~	3 hrs.
	☐ Opioid Awareness	2 hrs.
	☐ Preventing and Addressing Harassment and Sexual Miscon	
	☐ On-boarding: Guidance for the New Employee	
	☐ MRI Safety Training Level 1	
	☐ Developing your Goals	
	☐ Benefits Orientation - JHU Faculty and Staff	
	☐ Electronic Time and Attendance e210 (Recorded)	
☐ Johns Hopkins Institutional Review Boards (IRB) Compliance and Recertification Requirement	**Either: Initial Compliance Requirement** *(for PI and study team with HSR)* ☐ Human Subjects Research – Biomedical Research (CITI) ☐ Researchers (CITI) ☐ Conflict of Interest and Commitment (COI) ☐ Clinical Research Billing Orientation (CRBO)	11 hrs. for the bundle
	Or: Recertification Requirement *(for PIs and study team members every 3 years)* ☐ Refresher Course: An Overview of Research with Vulnerable Subjects (CITI) ☐ Refresher Course: Genetics Research (CITI) ☐ Refresher Course: Records Based Research (CITI) ☐ Good Clinical Practice and ICH (CITI)	20 hrs. for the bundle
☐ NIH/Institution Requirement	☐ Good Clinical Practice and ICH (CITI)	16 hrs.
	☐ Responsible Conduct of Research (CITI) *(every 4 years)*	7 hrs.

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Research Personnel Onboarding Program

- How? (Continue)
  - —Customize a training plan
    - Assign trainings (130-200 training hours!)
      - JHU and IRB requirements, GCP, clinical skills, DOT/IATA, Epic, REDCap, study conduct, soft skills
      - And more!
    - 1:1 Onboarding sessions (1-2 mentoring hrs. per week for 6-8 weeks)
    - (Optional), RCSS may continue with “Ongoing support” (Sample on Next Slide)
    - Follow up weekly and keep the supervisor informed
- Cost
  - —$65 per mentoring hour (approximately $500-$800)
  - —Monthly Invoices to the Internal Order number (IO#)

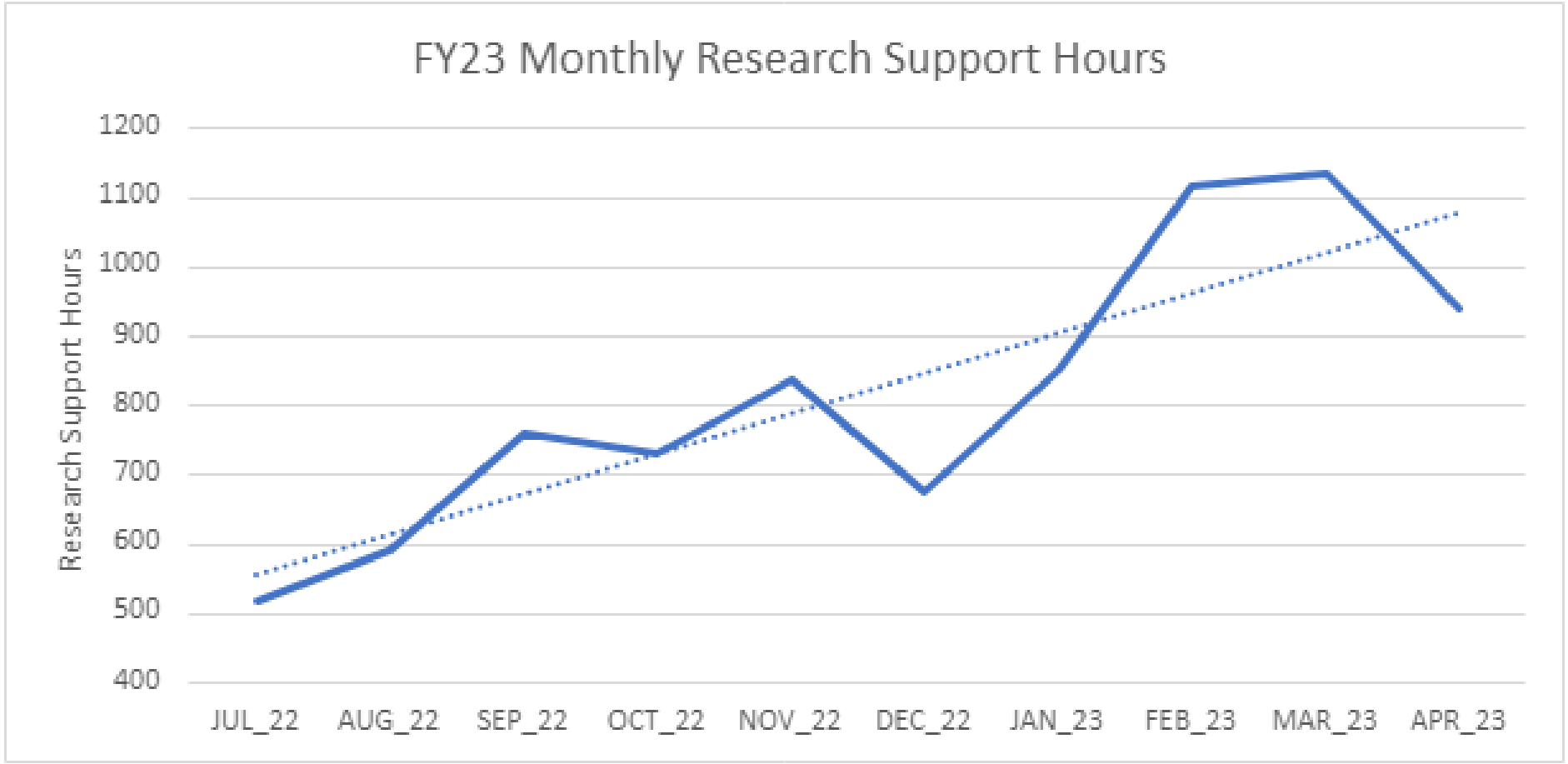
Ongoing Support (Optional)

☐ **Ongoing RCSS Support:** (Continuous RCSS oversight, support and guidance throughout the study process, Billing by hour)

☐ Site Selection and Activation	☐ Site Selection Visit (Qualification, Pre-Selection) ☐ Documents collection (Trainings, CVs, MLs, 1572, FDFs) ☐ Site Initiation Visit ☐ Logs completion (Training and DOAL)
☐ Study Conduct (Mentorship, step by step, on daily activities with a Senior Coordinator)	☐ Coordinator-Specific Protocol Review Guide ☐ Study Binder review, logs and documents organization. ☐ New Study team member-Documents collection (IRB Agree to participate, Training Log, DOAL, and documents collection) ☐ Screening and Inclusion/Exclusion confirming eligibility step by step ☐ Consenting (prep, process, documentation, Scanning to Epic, Future contact log, General status log) ☐ CRMS (Activation, Enrollment, and Billing) step by step ☐ Source Documents (CRFs), SOPs/MOPs creation and requirement ☐ Study Visit Conduct, step by step ○ Study visits - BEFORE (Reminders, Informed Consent Forms/Case Report Forms (ICF/CRFs) print, Schedule of Events, Coordinate with PI/team, Schedule procedures) ○ Study visits – DURING (Coordinate with PI/team, register participants in Interactive Response Technology (IRT), CRF completion, Capturing Adverse Events (AEs) Scheduling next visit, Receipts) ○ Study visits – AFTER (Processing and Shipping samples, Data Entry and queries resolution, Documenting Protocol Deviations, Note to Files, Adverse events and Serious Adverse Events reporting, Sponsor invoicing, participants' payments and reimbursements).

Supporting Research at JHU

- Over 8,100 research support hours in the last 10 months (>800/month)



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About Us

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JHU ClinicalTrials.gov Program

- 1.8 FTE
  - —Monitor >2,000 records across 4 PRS accounts
    - SOM, SON
    - SKCCC
    - JHSPH
    - All Children's
- Regularly assist other AMCs to develop programs
- Maintain 99% compliance and one of the top success rates of all academic sites

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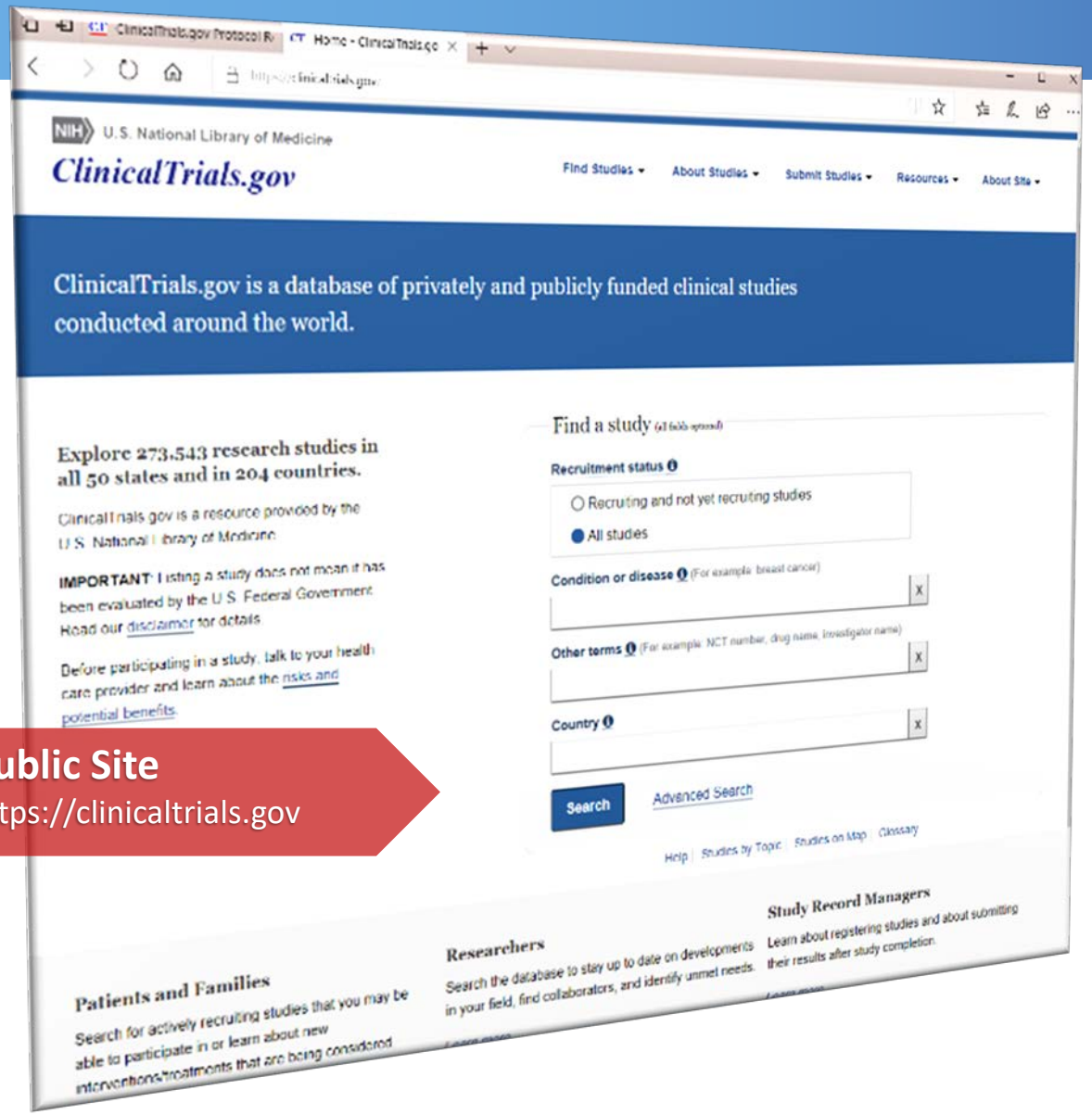
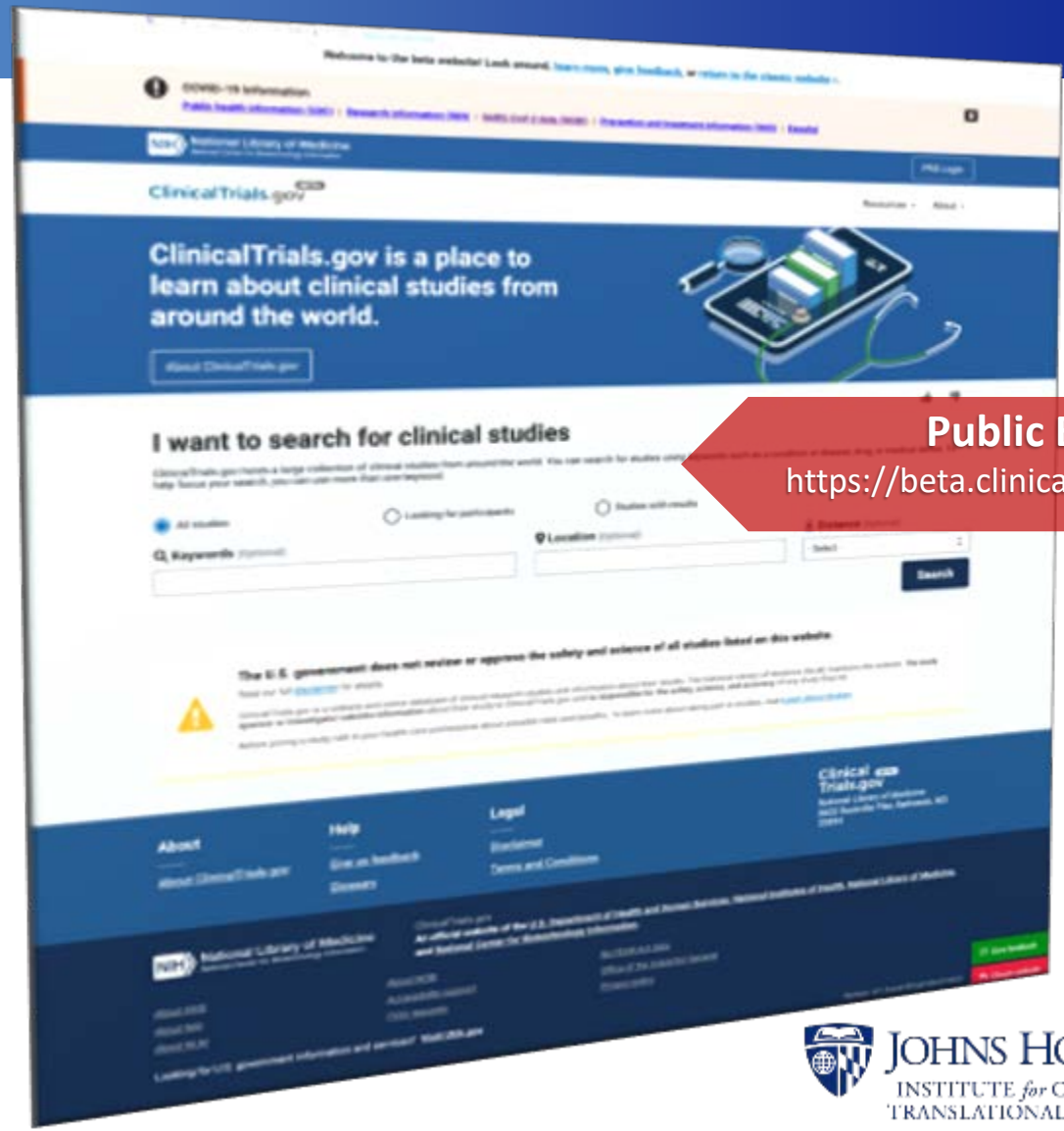
ClinicalTrials.gov – Public Site



Public Site
https://clinicaltrials.gov



Public Beta Site
https://beta.clinicaltrials.gov/

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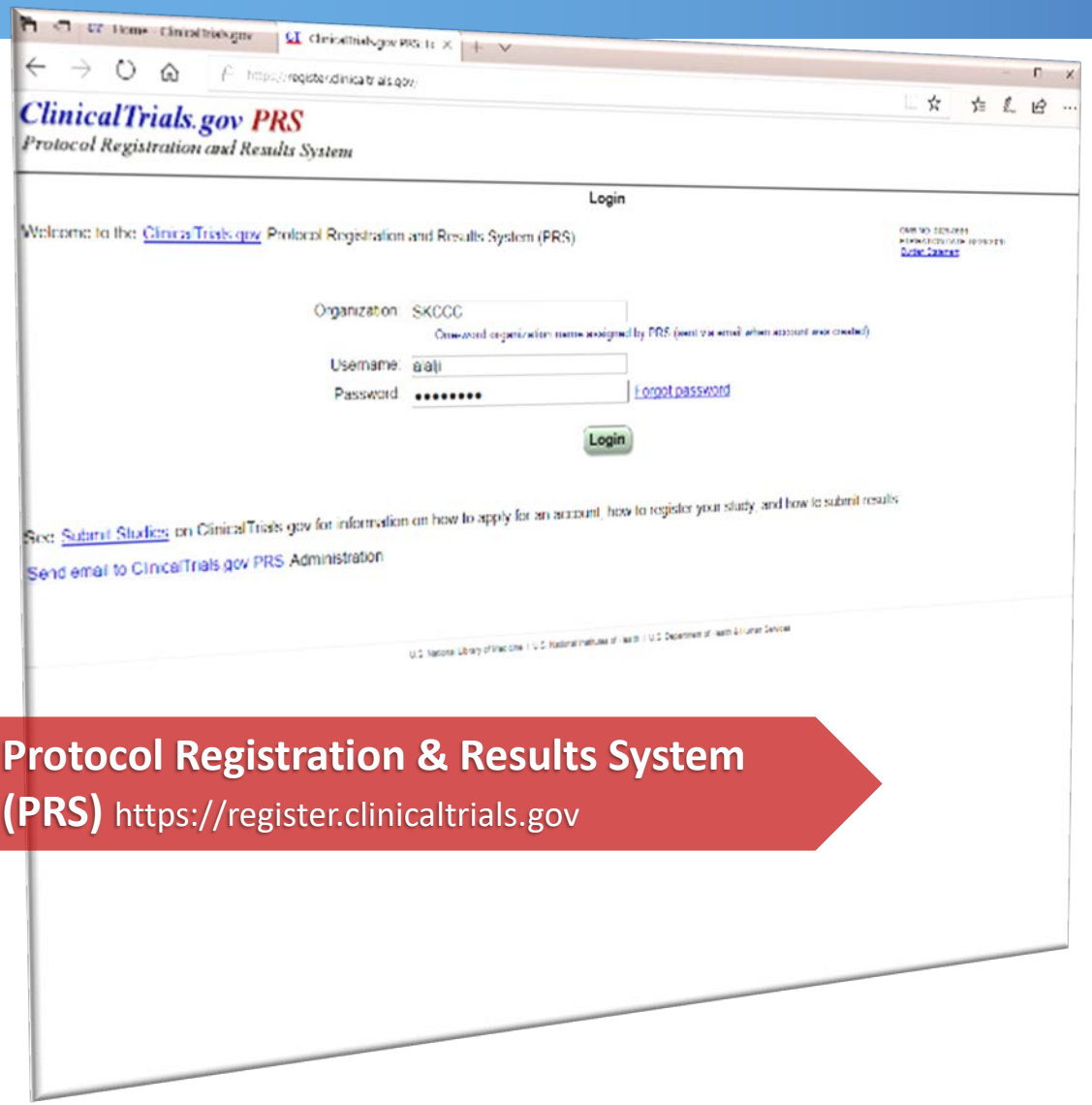
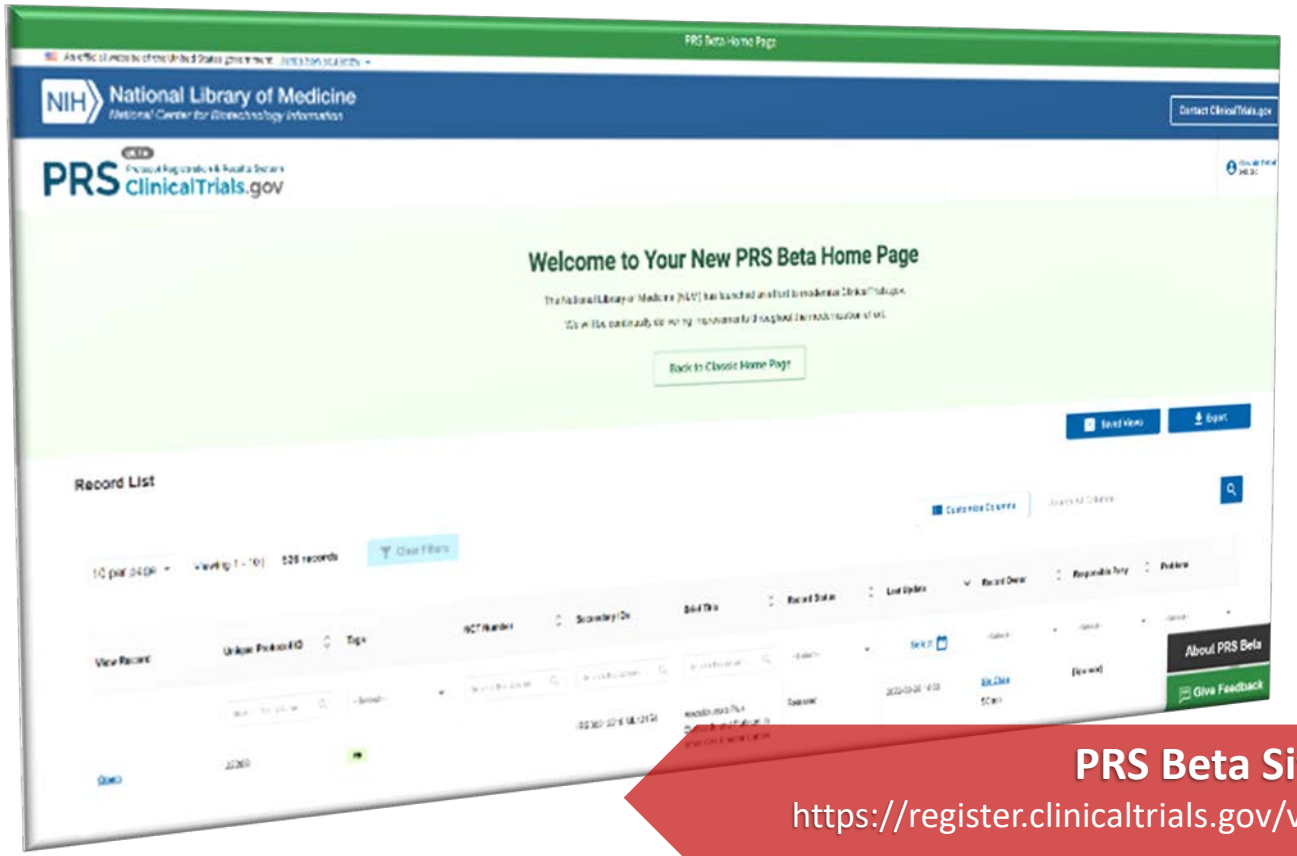
ClinicalTrials.gov - PRS



Protocol Registration & Results System (PRS) https://register.clinicaltrials.gov



PRS Beta Site
https://register.clinicaltrials.gov/v2/

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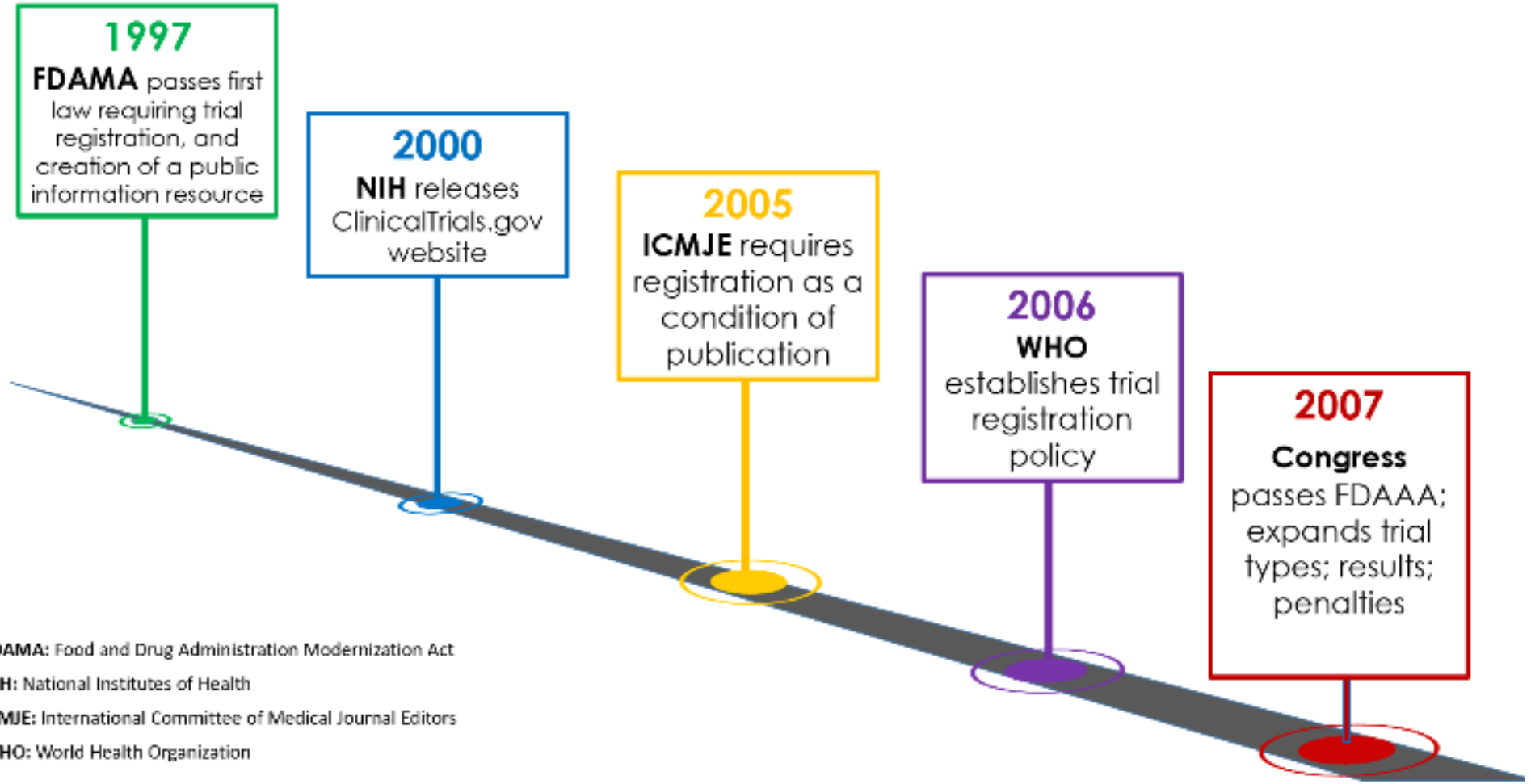
ClinicalTrials.gov Overview



FDAMA: Food and Drug Administration Modernization Act

NIH: National Institutes of Health

ICMJE: International Committee of Medical Journal Editors

WHO: World Health Organization

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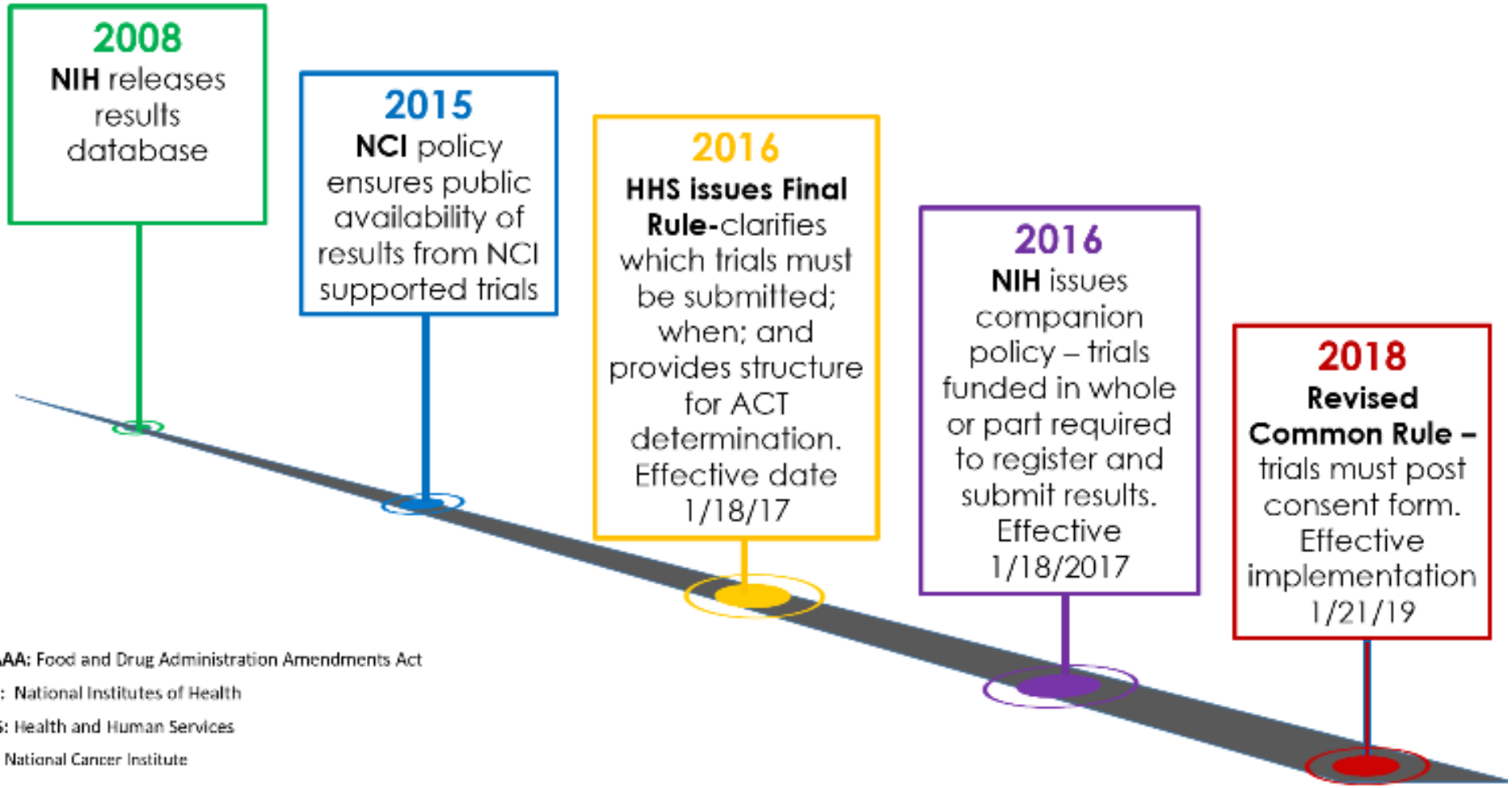
ClinicalTrials.gov Overview



FDAAA: Food and Drug Administration Amendments Act

NIH: National Institutes of Health

HHS: Health and Human Services

NCI: National Cancer Institute

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Why a ClinicalTrials.gov Program?

1.) Commitment to participants, scientific validity/transparency, responsible stewardship

2.) Avoid non-compliance penalties

- —Civil or criminal judicial actions
- —Civil monetary penalties up to $12,462 per study, per day
- —Withholding of current or future funding
- —Reputational risk (also upside!)

3.) Faculty support

- —Steep learning curve (institutional efficiency)*
- —Changing regulations and modernization

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*Keyes A, Mayo-Wilson E, Atri N, et al. Time From Submission of Johns Hopkins University Trial Results to Posting on ClinicalTrials.gov. *JAMA Intern Med.* Published online October 28, 2019. DOI: https://doi.org/10.1001/jamainternmed.2019.4710

Registration

- Due **prior to enrollment**
- Any research study meeting the definition of a clinical trial
  - International Committee for Medical Journal Editors (ICMJE)
  - Food and Drug Administration Amendments Act (FDAAA)
  - National Institutes of Health (NIH)
- Any research study with funding from an agency that requires registration
- Any research from a foundation that requires registration as a term or condition of the grant/award

Results Reporting

- Due **12 months after *primary completion date**** – Need to start 3-4 months early
- Results reporting reminders are sent to PI/Study team
- Assistance with results reporting
- Assistance with PRS reviewer comments (25 calendar days)
- Changes to PI/Study team (including when a PI leaves)
- Direct services at $50 per hour (optional)

* Final data collection date for primary outcome measure.

FDAAA 801 Violations

- Applies to Applicable Clinical Trials (ACT)
- Notices are is sent to the Responsible Party
  - —**Pre-Notice Letters** are **not** identified as an FDAAA 801 Violation and **not** identified in ClinicalTrials.gov
  - —**Notice of Noncompliance** Letters are identified as an FDAAA 801 Violation in ClinicalTrials.gov

https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

FDA Enforcement

- FDA has sent 53 **Pre-Notice Letters**
- **FDA has sent 4 Notice of Noncompliance** Letters

Responsible Party/Submitter	NCT Number	Notice of Noncompliance	Response Letter (if any)	Civil Money Penalty Amount (if any)
Ocugen	NCT03785340	4/15/2022	08/01/2022	
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021	12/20/2021	
Accuitis Inc.	NCT03064438	7/26/2021	05/26/2022	
Acceleron Pharma, Inc.	NCT01727336	4/27/2021	12/13/2021	

- FDA has, **so far**, not issues any civil monetary penalties

https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions#:~:text=FDA%20has%20the%20authority%20to,or%20misleading%20clinical%20trial%20information

FDA/NIH Enforcement

- August 2022 Office of Inspector General (OIG) Report

  "NIH did not ensure that all NIH-funded Intramural and Extramural clinical trials complied with Federal reporting requirements"

- FDA and NIH are working together to identify and target noncompliance
- NIH has sent >300 Noncompliance Letters

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

October 19, 2022
XXX, Authorized Official
Johns Hopkins University

Reference [Grant #]

Dear XXX,

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: XXX
PI Name: XXX
Period of Performance: XXX-XXX
NIH Institute/Center: NIDA

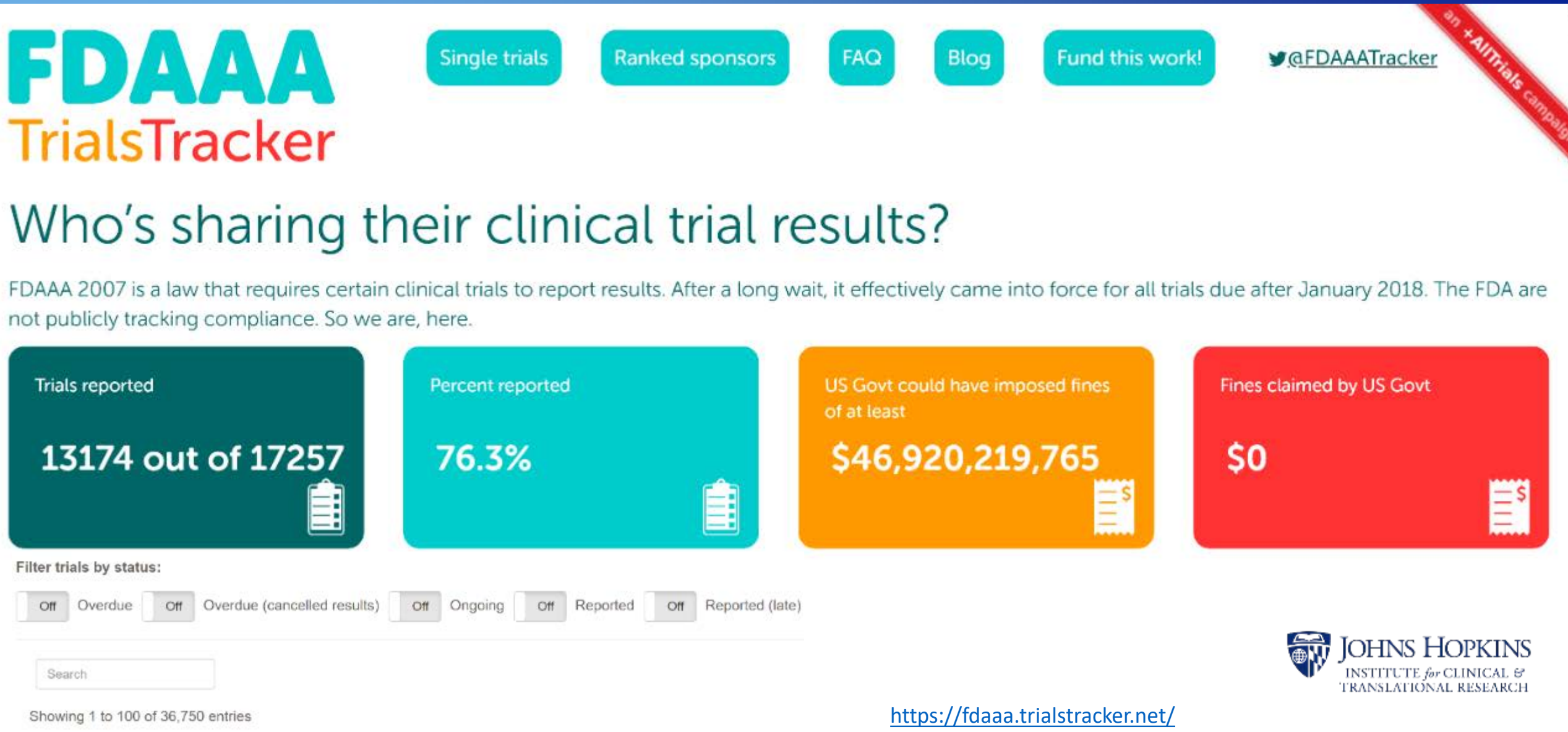
The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

NCTXXXXXXXX
[Study Title]
Primary Completion Date: XX/XX/XX

Compliance with the NIH policy is a term and condition of this grant award; however, NIDA has been unable to verify that results information has been submitted to ClinicalTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

https://oig.hhs.gov/oas/reports/region6/62107000.asp

FDAAA TrialsTracker



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https://fdaaa.trialstracker.net/

2023 Articles

Congress demands that FDA and NIH sanction sponsors that fail to report clinical trial results

FDA is petitioned to boost enforcement of trial sponsors that fail to register studies or report results

NIH waste far over $100 million in medical research funding every year – new study

https://www.transparimed.org/single-post/fdaaa-pallone
https://www.statnews.com/pharmalot/2023/02/27/fda-petition-clinical-trials-transparency-nih/
https://www.transparimed.org/single-post/nih-research-waste

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Summary of Requirements

Entity	Registration	Results Reporting	Penalties
Health and Human Services (HHS)	Within 21 days of enrollment	Within 365 days of primary completion date for ACTs	• $13,237/study/day • Criminal proceedings • Loss of grant funding
National Institutes of Health (NIH)	Within 21 days of enrollment	Within 365 days of primary completion date for clinical trials receiving NIH funding	Loss of grant funding (to include the institution)
National Cancer Institute (NCI)	Within 21 days of enrollment	Within 365 days of primary completion date of NCI-supported clinical trials (in a peer-reviewed journal and/or ClinicalTrials.gov)	Loss of grant funding
Veterans Health Administration (VHA)	Prior to release of funding. Prior to enrollment	Within 365 days of primary completion date	Loss of grant funding

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Summary of Requirements

Entity	Registration	Results Reporting	Penalties
Centers for Medicare & Medicaid Services (CMS)	All qualifying clinical trials	Study-specific	• Coverage denial • Costs and fraud investigations
Patient-Centered Outcomes Research Institute (PCORI)	All Clinical studies (including observational)	Expected of all PCORI Clinical studies – 500 word abstract published on PCORI website	• Loss of grant funding
International Committee of Medical Journal Editors (ICMJE)	Prior to enrollment		Ineligibility to publish
Department of Defense (DoD)	Prior to enrollment. Prior to release of funding.	Study-specific	• Withholding or recovery of award funds

Responsible Party

"Responsible party means, with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3; or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information."

https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part11.xml
https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#h-51

Responsible Party

▼ 3. Sponsor/Collaborators

Responsible Party, by Official Title *

Definition: An indication of whether the responsible party is the sponsor, the sponsor-investigator, or a principal investigator designated by the sponsor to be the responsible party. Select one.

- Sponsor: The entity (for example, corporation or agency) that initiates the study
- Principal Investigator: The individual designated as responsible party by the sponsor (see Note)
- Sponsor-Investigator: The individual who both initiates and conducts the study

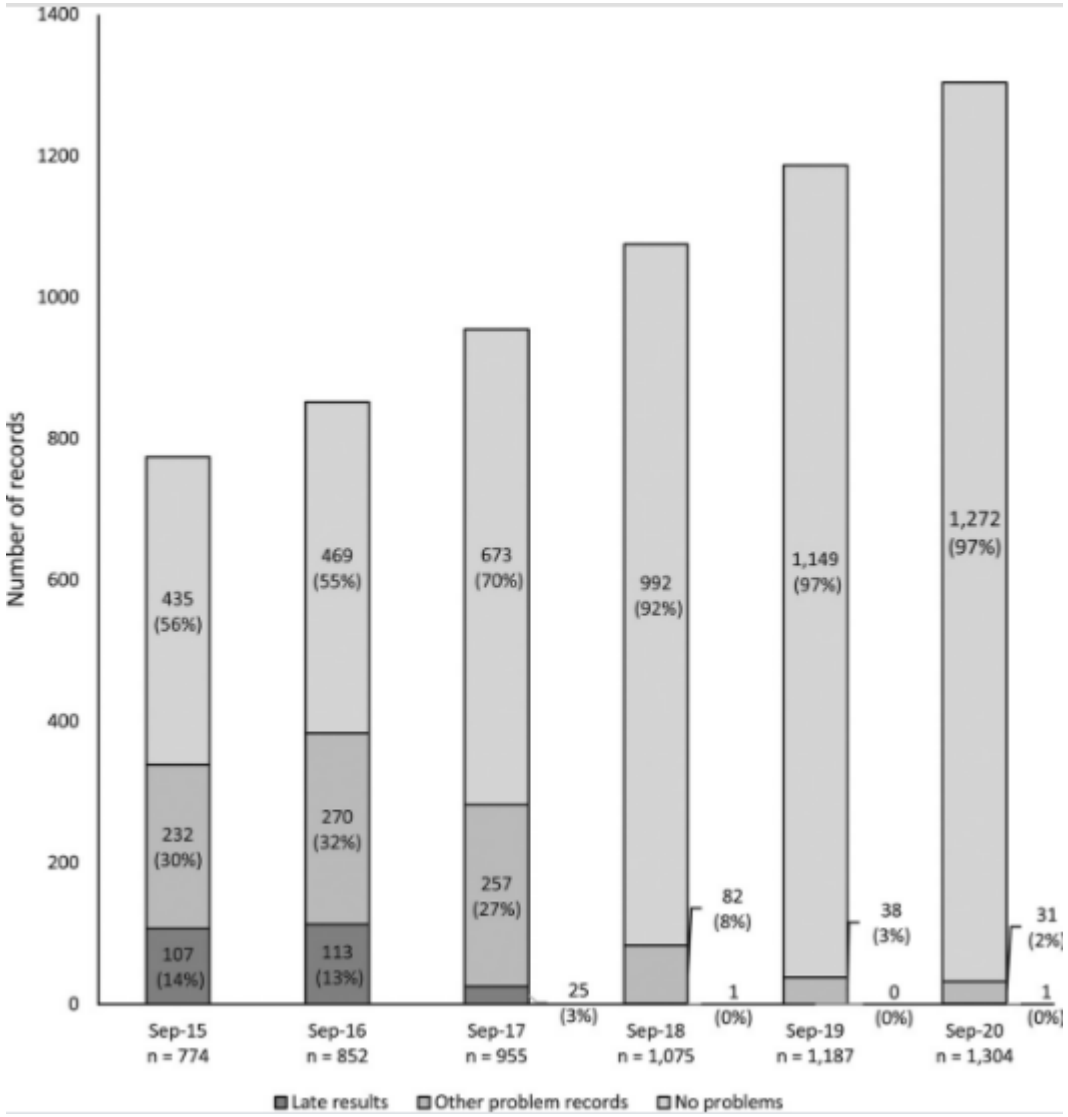
Note: The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following requirements: is responsible for conducting the study; has access to and control over the data from the study; has the right to publish the results of the study; and has the ability to meet all of the requirements for submitting and updating clinical study information.

Requirements:

- Registration
- Review comments
- Timely updates
- Addressing problems
- Annual Verification
- Anticipated dates
- Uploading consent form
- Results entry

https://register.clinicaltrials.gov/prs/html/definitions.html?popup=true#Sponsors

JHU ClinicalTrials.gov Program(s)



SOM

- In 2015 we had one of the worst compliant rates at 44% (339/774)
- By 2017 we improved to 30% (282/955)
- Since 2020 we maintain consistently <1%
- Manuscript published

SKCCC

- In 2018 compliance was 48% (212/442)
- By 2020 we improved to 3% (16/489)
- Since 2021 we maintain consistently <2%
- Manuscript pending

Creating a Program to Support Registering and Reporting Clinical Trials at Johns Hopkins University Keyes A, Mayo-Wilson E, DPhil PN, Lalji A, Tetteh O, Ford DE. Academic Medicine, Vol. 96, No. 4/ April 202. DOI: 10.1097/ACM.0000000000003806

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JHU ClinicalTrials.gov Program

- Developed a Quality Review Checklist

	Pre-checklist	Post-checklist	p value
Registration, N	**107**	**104**	
Success rate (%)	44.86	79.81	<0.001
Submission cycles, mean (SD)	1.74 (0.78)	1.22 (0.46)	<0.0001
Total days in review, mean (SD)	18.90 (26.72)	2.12 (3.85)	<0.0001
Results—Overall, N	**44**	**22**	
Success rate (%)	11.36	40.91	0.010
Submission cycles, mean (SD)	2.23 (0.68)	1.64 (0.58)	0.0011
Total days in review, mean (SD)	115.80 (129.33)	39.27 (19.84)	<0.0001

CLINICALTRIALS.GOV JHU RECORD REVIEW

PROTOCOL ID	RECORD OWNER	REVIEWER	❑ Registration ❑ Update status ❑ Results (add Results checklist)	❑ pACT/ACT ❑ Non-ACT
NCT#				

DATE RELEASED	COMMENTS DATE	REPLY DATE	DATE PUBLISHED

GENERAL REVIEW ITEMS — **NOTES**

- ❑ No monetary value (e.g. compensation, food voucher) entered anywhere in the protocol
- ❑ Record Owner is the PI (JHU Policy)
- ❑ PI on record matches IRB PI: _____
- ❑ Contact info for Record Owner is up-to-date
- ❑ NCT number included in IRB "Clinical Trials Information" section (if applicable)
- ❑ All Warnings (if needed)
- ❑ All parenthetical citations have been removed
- ❑ All acronyms have been expanded on their first use
- ❑ Spell-check complete
- ❑ Free-text fields are blank if there is no information to report, and do not contain text such as "TBD," "Pending," "N/A," "None"

PROTOCOL SECTION

STUDY IDENTIFICATION

- ❑ Unique protocol ID is the IRB number (JHU Policy)
- ❑ Brief Title does not include study type (e.g., Phase I, Randomized...)
- ❑ Official title should match what is in the IRB (or grant application if applicable)
- ❑ Secondary IDs include NIH grant numbers (verify in IRB)

STUDY STATUS

- ❑ Record Verification Date is the current month/year
- ❑ Overall Status matches IRB/CRMS
- ❑ Study start date verified with CRMS enrollment date
- ❑ Completion Dates Actual/Anticipated have been evaluated for accuracy
- ❑ If timeframes for outcomes are the same the primary and study completion dates are identical

SPONSOR/COLLABORATORS

- ❑ Responsible Party: Sponsor (JHU Policy)
- ❑ All sources of support identified in IRB "Support Information" section included as Collaborators
- ❑ Full Name used and if not recognized, "Recognize" is selected

Tetteh, O., Nuamah, P., Keyes, A. Addressing the quality of submissions to ClinicalTrials.gov for registration and results posting: The use of a checklist. *Society of Clinical Trials.* Published online August 5, 2020. https://doi.org/10.1177/1740774520942746

Johns Hopkins Institute for Clinical & Translational Research

JHU ClinicalTrials.gov Program

- Completed a user satisfaction survey
  - —Guide educational content development
  - —Developing video tutorials
- Preparing a follow-up manuscript for developing a program within SKCCC
- Partnering with University of Maryland Baltimore
  - —Customizing the Checklist
  - —Current educational series
- Congratulating Oswald for Matching!

JOHNS HOPKINS
INSTITUTE for CLINICAL & TRANSLATIONAL RESEARCH

Continued Success

- We review ~200 records each month and run compliance reports
  - —Each record gets reviewed prior to release
  - —Monthly reports identify problems BEFORE they occur
  - —Run monthly IRB reports (change in PI, terminated/expired, no NCT)
  - —We need timely responses from PIs/study teams to ensure compliance
- Departing faculty
  - —Nationwide the biggest barrier
  - —Complete the Departing Faculty Checklist/Resignation Questionnaire
- Schedule a Departmental Meeting
  - —Inform your PIs/study teams
  - —Departmental compliance reports

ClinicalTrials.gov Taskforce

- 650 members, 220 Academic Centers
- Monthly Meetings (NLM, FDA, OHRP, NCI, NCATS)
- Many best practices developed
- Active listserv
- Revamping website to be ADA accessible
- Ongoing initiatives (i.e., dashboard for CTSA PIs, train the trainer, follow-up survey*)

*Mayo-Wilson, E., Heyward, J., Keyes, A. *et al.* Clinical trial registration and reporting: a survey of academic organizations in the United States. *BMC Med* 16, 60 (2018) doi:10.1186/s12916-018-1042-6

https://ctrrtaskforce.org/

Co-Leads: Sarah White, MRCT; Tony Keyes, JHU

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Questions

- https://ictr.johnshopkins.edu/service/study-conduct/rcss/
- akeyes1@jhmi.edu

- https://ictr.johnshopkins.edu/service/regulatory/ct-gov/
- registerclinicaltrials@jhmi.edu