CLINICAL TRIALS REGISTRATION AND RESULTS REPORTING TASKFORCE

General Resource

Professional Development Opportunities for PRS Administrators

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Purpose

ClinicalTrials.gov Registration and Results Reporting Taskforce members join with a wide range of experience from highly variable organizational structures each with unique institutional goals. Despite this reality, **Taskforce members facilitate a common end goal**: to meet an ethical obligation to participant and scientific communities and the public as they benefit from improved health outcomes. This database is an important part of Human Research Protection Programs and consequently building community trust. The common end goal informs professional development opportunities for Protocol Registration and Results System (PRS) Administrators.

This document is a resource for PRS Administrators to use in their professional development conversations. *It is not intended to be a list of required skills for a job description*.

Opportunities

Direct ClinicalTrials.gov PRS Educational Opportunities

Basics of ClinicalTrials.gov and registration, maintenance, and results submission.

- CITI Training on ClinicalTrials.gov
- Train the Trainer Workshop at NIH
- Participate in the Clinical Trials Registration and Reporting Taskforce for continuing education and collaboration opportunities
- PRS Help Resources
- ClinicalTrials.gov fictional manuscripts and example ClinicalTrials.gov records

Get Familiar with Regulations, Policy, and Guidance (Reporting Requirements)

FDAAA Law for Applicable Clinical Trial (ACT) reporting – enlist institutional legal counsel for interpretation of FDAAA Law and develop an auditing group to reach consensus on whether studies are registered as ACTs.

- Section 801 of the Food and Drug Administration Amendments Act (FDAAA)
- 42 CFR Part 11 – the "Final Rule"
- NIH Policy on the Dissemination of NIH-funded Clinical Trial Information
- Connect with staff working in Application Submission System & Interface for Submission Tracking (ASSIST) to learn about this system and how it maps to the ClinicalTrials.gov record
- Use ASSIST to verify NIH-funded studies are registered properly
- Identify NIH-funded studies at your institution at NIH RePORTER
- Centers for Medicare and Medicaid Services (CMS) qualifying clinical trials
- Revised Common Rule for Informed Consent Form (ICF) upload
- US Department of Veterans Affairs – Office of Research and Development (VA ORD) funded clinical trials
- Patient Centered Outcomes Research Institute (PCORI) funded clinical trials

Best Practices in Clinical Trial Transparency

PRS Administrators help their institutions meet legal and policy requirements for registration, maintenance, and results reporting. Best Practices in Clinical Trial Transparency go above and beyond these requirements to meet ethical obligations for all communities involved in their conduct and interested in their results. Find information:

- Via the World Medical Association Declaration of Helsinki
- Via the World Health Organization
- Via the International Committee of Medical Journal Editors (ICMJE)
- Increase education around transparency best practices at your institution

Plain Language

Plain Language is direct and easy to understand. It requires communicating in an active voice with simple words and helpful formatting. Plain language helps you:

- Communicate science to the public on ClinicalTrials.gov
- Improve email response rates
- Present effective institutional outreach and education
- Create useful institutional web content and resources
- Convey subject matter expertise at conferences

Read the results of a study summarizing the use of Plain Language on ClinicalTrials.gov

Plain language courses may be available at your institution.

ClinicalTrials.gov provides a Plain Language Guide to Write a Brief Summary

Basics of Clinical Trial Conduct

Understand the collaborative efforts at your institution to develop, review, approve, amendment, coordinate, monitor, audit, and analyze the results of a clinical trial to engage the right people with your questions about the public record.

- Protocol Development - Elements of a Clinical Trial Protocol
- Pre-award and Post-award Process - eRA Commons and the ASSIST system
- Regulatory Process - Human Research Protection Program Resources
- Study Coordination
- Monitoring and Auditing process
- Results Analysis
- Good Clinical Practice

Institutional Specific Policies, Procedures, Resources as Learning Opportunities

- Learn / Initiate institutional compliance procedures for support, learn compliance operations
- Create / Influence policy for escalation as necessary for non-compliance
- Leverage institutional culture (mission, vision, values) to propose systems or process, learn to advocate for the resources and ideas you are pursuing
- Understand institutional resources to improve your workflow, learn a new application, familiarize yourself with institutional clinical trials management system
- Propose, develop, or update Standard Operating Procedures and Work Instruction for PRS Administrators
- Propose or develop ClinicalTrials.gov institutional metrics, reports, dashboards
- Leverage Clinical Trials Management System Reporting, understand data field definitions important to your work

- Leverage reports from your Institutional Review Board (IRB) application to QA protocol amendments

Basic Statistical Language

Improve your understanding of statistical language to better assist with summary results reporting

- LinkedIn Learning offers basic statistics courses
- Connect with a biostatistician at your institution
- Educate study teams on the statistical analysis data fields (template linked under Resources on this page) available in the outcome measures section

Sourcing Public Data

The ClinicalTrials.gov site is an enormous database that you can mine to create resources or benchmarks for your institution using:

- Data aggregators, like from Aggregate Analysis of ClinicalTrials.gov (AACT)
- Basic data query languages and functions
- Basic concepts of APIs
- Complex Search Queries using the Expert Search function

LinkedIN Learning offers courses on the above topics.

Eyes on the Future

Consider international organizations and modern topics relevant to clinical trials as a personal development opportunity.

- Clinical Trials Transparency – Advocacy
    - AllTrials
    - Sense About Science - USA

- Limitations of AI – Research proposed uses of AI in clinical trials reporting to share the limitations with your institution
    - TrialGPT – proposed AI solution to match participants with clinical trials
    - Using AI to create plain language summaries of clinical trial results
- Transforming Trials 2030 – Clinical Trials Transformation Initiative

Conferences Relevant to PRS Administrators

- Society of Clinical Research Associates (SOCRA)
- Association of Clinical Research Professionals (ACRP)
- Society of Research Administrators (SRA)
- Association for Accreditation of Human Research Protection Program (AAHRPP)
- Health Care Compliance Association (HCCA)
- Drug Information Association (DIA) Global Clinical Trial Disclosure and Data Transparency Conference
- Public Responsibility in Medicine and Research (PRIM&R)
- National Council of University Research Administrators (NCURA)
- Project Manager Institute

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