PRS Protocol Registration & Results System
ClinicalTrials.gov

To learn more about the topics in the *How Does ClinicalTrials.gov Fit into the Clinical Trial Disclosure Landscape?* video, visit these resources:

- Clinical Trials: Read about the International Committee of Medical Journal Editors (ICMJE) policies regarding clinical trial registration and data sharing statements for journal submissions. (Source: ICMJE)
- FDAAA 801 and the Final Rule: Read a summary of the clinical trial registration and results information submission requirements described in FDAAA 801 and the Final Rule. (Source: ClinicalTrials.gov)
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information: Read about the purpose, scope, and applicability of this policy.
- R2805CP: Download a PDF file to read about the mandatory reporting of an 8-digit clinical trial number on Medicare claims. (Source: Centers for Medicare and Medicaid Services)
- ORD Sponsored Clinical Trials: Registration and Submission of Summary Results: Find resources for research administrators that support the registration of clinical trials sponsored by the U.S. Department of Veterans Affairs (VA) Office of Research and Development and the submission of summary results. (Source: VA)
- Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (PDF) and Frequently Asked Questions - Responsible Party: Learn more about how to determine the responsible party for a study. (Source: ClinicalTrials.gov)
- Frequently Asked Questions - Updates to Clinical Trial Information: View a list of clinical trial registration data elements that should be updated more frequently on ClinicalTrials.gov. (Source: ClinicalTrials.gov)
- Guidance Document: Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank (August 2020): Find guidance for responsible parties, submitters of certain applications and submissions to the U.S. Food and Drug Administration (FDA), and FDA staff. (Source: FDA)
- Glossary of Common Site Terms: Consult a glossary to help you understand words and phrases that are frequently used on ClinicalTrials.gov. (Source: ClinicalTrials.gov)
- FDAAA TrialsTracker: Use this tracker created by the Evidence Based Medicine DataLab at the University of Oxford to see whether a clinical trial is in compliance with FDAAA 2007 regarding reporting results. (Source: FDAAA TrialsTracker)