ClinicalTrials.gov PRS

Protocol Registration and Results System

PRS Study Record Basics Resources

To learn more about the topics in the *PRS Study Record Basics* video, visit these resources:

- Support Materials: Find data element definitions and resources related to study registration and results submission, as well as links to relevant laws and policies. The page also includes links to external resources on the websites of organizations such as the U.S. Food and Drug Administration and the International Committee of Medical Journal Editors. (Source: ClinicalTrials.gov)

PRS User and PRS Administrator Help:

- PRS User's Guide: Learn how to use the PRS, and review step-by-step instructions for PRS functions. (Source: ClinicalTrials.gov PRS)

- ClinicalTrials.gov Protocol Registration Quality Control Review Criteria: Read an overview of the ClinicalTrials.gov registration quality-control (QC) review process, and view specific criteria intended to help you prepare study records with protocol registration information. (Source: ClinicalTrials.gov)

- ClinicalTrials.gov Results Quality Control Review Criteria: Read an overview of the ClinicalTrials.gov results QC review process, and view specific criteria intended to help you prepare study records with results information. (Source: ClinicalTrials.gov)

- PRS Guided Tutorials: Review step-by-step instructions for entering study registration and results information in the PRS. (Source: ClinicalTrials.gov PRS)

Templates and Checklists:

- Interventional Study Protocol Registration Template

- Observational Study Protocol Registration Template

- Expanded Access Protocol Registration Template

- Simple Results Templates and Results Data Preparation Checklists

Data Element Definitions:

- Protocol Registration Data Element Definitions

- Expanded Access Data Element Definitions

- Results Data Element Definitions