Since the Food and Drug Administration Amendments Act of 2007, the scope required of clinical trials to be registered and the requirements of reporting results on ClinicalTrials.gov have expanded. The clinical trials nurse (CTN) may be directly involved with any part of this process. In this session, you’ll explore the rationale for the registry and how data are reported to comply with the law and better answer patient questions related to information found on the website.

Target Audience: Clinical Trial Nurses

Level of Content: Introductory

Coordinator:
Elizabeth Ness, MS, BSN, RN
Nurse Consultant (Educator)
Center for Cancer Research
Bethesda, MD
nesse@mail.nih.gov

Full Disclosure:
Nothing to Disclose

Speaker:
Rebecca Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov
National Library of Medicine, National Institutes of Health
Bethesda, MD
williamsre@mail.nih.gov

Full Disclosure:
Nothing to Disclose

Objectives:
At the end of this session, participants will be able to:
1. Discuss the scientific and ethical rationale behind registering clinical trials and reporting results.
2. Define which trials are required to be registered and submit results to ClinicalTrials.gov.
3. Discuss the process for submitting results to ClinicalTrials.gov.
4. Identify resources to assist with registration and results submissions.