Clinical Trial Registration Decision Tree: Step 1

Here is a clinical trial registration decision tree to help you determine how your trial should be registered in accordance with FDA Amendments Act of 2007.

Step 1:
Is the study an applicable Clinical trial?

Is this a (1) Trial of a Drug or Biologic: A Controlled, Clinical investigation, other than a Phase 1 investigation, of a product subject to FDA regulation
Or
(2) A Controlled trial with health outcomes, other than A small feasibility study, or pediatric postmarket surveillance?

No

No need to register
Stop here

Yes

Proceed to Step 2
Step 2: Who is the “responsible party” to register it on clinicaltrials.gov?

- Is the protocol initiated by an industry sponsor?
  - Yes
  - No
    - Is the protocol initiated by WU investigator or an outside investigator?
      - Initiated by WU investigator
        - The PI registers study
      - Initiated by an external investigator
        - External PI registers study

Sponsor registers study

Clinical Trial Registration Decision Tree: Step 2