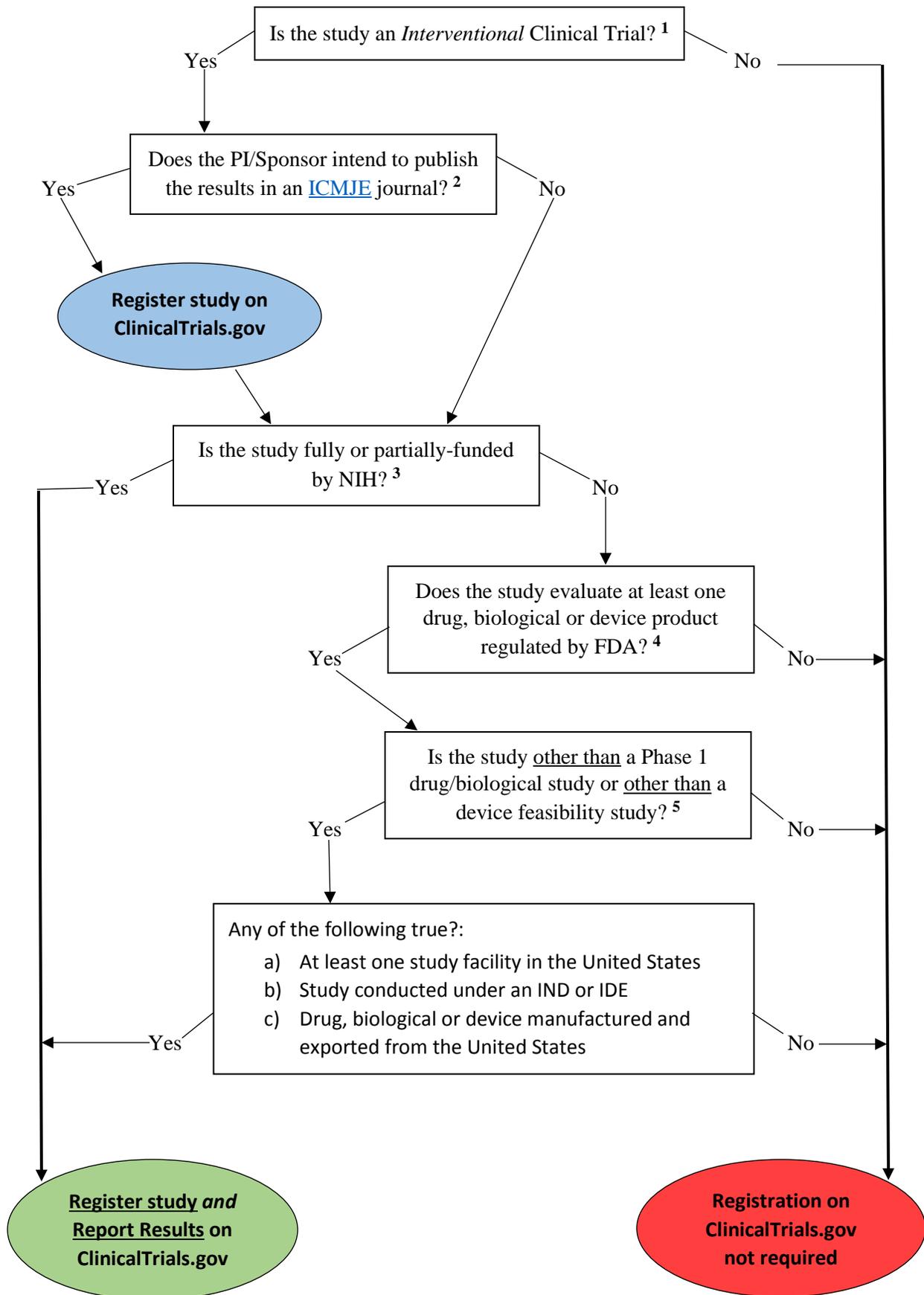


ClinicalTrials.gov Registration and Results Reporting Decision Tree



1. Is the study an Interventional Clinical Trial?

An intervention is defined as a manipulation of the subject or the subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include

- Drugs, small molecules or compounds
- Biologics
- Devices
- Procedures (e.g., surgical techniques)
- Delivery systems (e.g., telemedicine, face-to-face interviews)
- Behavioral strategies (e.g. diet, cognitive therapy, exercise, development of new habits)
- Treatment strategies
- Prevention strategies
- Diagnostic strategies

In a clinical trial, *interventional* is defined to mean that human subject participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health-related outcomes.

2. Does the PI/Sponsor intend to publish results in an ICMJE journal?

A complete list of journals that follow the International Committee of Medical Journal Editors (ICMJE) recommendations for the conduct, reporting, editing and publication of scholarly work in medical journals can be found [here](#). **ICMJE standards require registration of clinical trials in a public trials registry (ClinicalTrials.gov) at or before the time of first patient enrollment as a condition of consideration for publication.** More information about ICMJE and registration requirements can be found on the [ICMJE website](#).

3. Is the study fully or partially funded by NIH?

The NIH defines a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of these interventions on health-related biomedical or behavioral outcomes. The [NIH Policy](#), effective January 18, 2017, requires all investigators conducting clinical trials funded by the NIH to register and report results of these trials at ClinicalTrials.gov.

The NIH policy is applicable to all clinical trials funded in whole or in part by the NIH, regardless of study phase, intervention type (including behavioral interventions), or whether they are investigating an FDA regulated drug, biologic or device.

4. Does the study evaluate at least one drug, biological or device product regulated by FDA?

This includes clinical trials that investigate a drug or biological product that is the subject of an approved new drug application (NDA) or biologic license application (BLA) or that would require an approved NDA or BLA to be legally marketed in the United States. The [FDA Orange Book](#) provides a list of licensed drug products with FDA approval. The [FDA Purple Book](#) provides a list of licensed biological products with FDA approval.

Also included for this criteria are clinical trials that investigate a device for which approval by the FDA has been attained or is being sought; these are device products subject to the Food, Drug & Cosmetic Act regulations (510(k), 515, or 520(m)). [The FDA Medical Devices website](#) provides lists and searchable databases for FDA-approved devices.

5. Is the study other than a Phase 1 drug/biological study or other than a device feasibility study?

Phase 1 trials include studies that introduce an investigational new drug into humans, have primary objectives of safety measurements, may include normal volunteer subjects, can be designed to determine the metabolism and pharmacologic actions of the drug, study the side effects associated with increasing doses, and if possible, gain early evidence on effectiveness. A device feasibility study is a limited clinical investigation of a device early in development, typically before the device design has been finalized, for a specific indication. Phase 1 clinical trials and device feasibility studies are exempted from FDA requirements for ClinicalTrials.gov registration and results reporting. For additional details, refer to the [Applicable Clinical Trial Checklist](#).