

What clinical studies should be posted on a website (www.clinicaltrials.gov)?

A clinical study should be posted on www.clinicaltrials.gov if any of the boxes below are checked.

Definitions per ICMJE

Medical intervention means any intervention used to modify a health outcome. The definition includes drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

Clinically directive: trials whose primary purpose is to affect clinical practice

Any research project that:

- Prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome
- "Clinically directive"
- Phase II study that is clinically directive
- Phase III study
- Phase IV study
- Trials that have at least one prospectively assigned concurrent control or comparison group

Clinical studies that do not require website registration per ICMJE

If any of these boxes are checked, the study does not require website registration.

- Trials whose primary requirement is to assess major unknown toxicity
- Trials whose primary requirement is to assess pharmacokinetics (Phase I)