Who is required to register on ClinicalTrials.gov

Clinical trials registration and results reporting is required by law for all Applicable Clinical Trials, for clinical trials funded by NIH, and for investigators wishing to publish trial information in an ICMJE journal. The Responsible Party (sponsor) of a clinical trial is the person who initiates the trial.

Overview of ClinicalTrials.gov Reporting Policies

Element	Final Rule	NIH Policy	ICMJE Policy
Scope/Applicability	Applicable clinical trials of FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act. Does not apply to phase 1 trials or small feasibility studies. Applicable clinical trials are (1) clinical trials of drug and biological products that are controlled, clinical investigations, other than phase 1 investigations of a product subject to FDA regulation; and (2) prospective clinical studies of health outcomes comparing an intervention with a device product against a control in humans (other than small feasibility studies) or any pediatric post-market surveillance studies required by FDA under the FD&C Act. Applies to public and private sector sponsors and other entities who meet the definition of a responsible party.	All clinical trials funded wholly or partially by NIH. Includes phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions. Applies to NIH-funded clinical trials where applications or proposals are received by NIH on or after the policy's effective date. Applies to NIH-conducted clinical trials initiated on or after the policy's effective date.	All clinical trials which wish to publish in an ICMJE journal, or its affiliates, must register prior to enrolling the first subject. As of July 1, 2018, manuscripts submitted to ICMJE journals must contain a data sharing statement. As of July 1, 2019, this statement must also be present in the ClinicalTrials.gov record.
Timeframe for registration on ClinicalTrials.gov	Not later than 21 days after enrollment of the first participant.	Not later than 21 days after enrollment of the first participant.	Prior to enrollment of first subject.
Registration data elements to be	Elements defined in the final rule. Consists of descriptive information, recruitment information,	Elements defined in the final rule. Consists of descriptive information, recruitment information, location and	Elements defined in the final rule. Consists of descriptive information, recruitment

Element	Final Rule	NIH Policy	ICMJE Policy
submitted to ClinicalTrials.gov	location and contact information, and administrative data.	contact information, and administrative data.	information, location and contact information, and administrative data.
Timeframe for results information submissions to ClinicalTrials.gov	Not later than 12 months after primary completion date; possible delay of up to an additional 2 years for trials of unapproved products or of products for which initial FDA marketing approval or clearance is being sought, or approval or clearance of a new use is being sought.	Not later than 12 months after primary completion date; possible delay of up to an additional 2 years for trials of unapproved products or of products for which initial FDA marketing approval or clearance is being sought, or approval or clearance of a new use is being sought.	Not mandated in policy but must meet the requirements of FDAAA 801.
Results data elements to be submitted to ClinicalTrials.gov	Elements defined in the final rule. Includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol, and statistical analysis plan, and administrative information.	Elements defined in the final rule. Includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol, and statistical analysis plan, and administrative information.	Elements defined in the final rule. Includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol, and statistical analysis plan, and administrative information.
Potential Consequences of Non-compliance	• Identifying clinical trial record as non-compliant in ClinicalTrials.gov • For Federally funded trials, grant funding can be withheld if required reporting cannot be verified. • Civil monetary penalties of up to $14,724 per day	• May lead to suspension or termination of grant or contract funding • Can be considered in future funding decisions • Identifying clinical trial record as non-compliant in Clinical Trials.gov	• Inability to publish in ICMJE or affiliated journal