

History of the Clinical Trial Transparency and Disclosure Landscape Resources

To learn more about the topics in the History of the Clinical Trial Transparency and Disclosure Landscape video, visit these resources:

- [Clinical Trials](#): Read about the ICMJE policies on clinical trial registration and data sharing statement requirements for journal submissions. (Source: ICMJE)
 - ICMJE clinical trial registration and data sharing statement policies:
 - To promote the ethical obligation to responsibly share trial data
 - ClinicalTrials.gov: [IPD Sharing Statement data element](#)
 - Condition for publication of trial results (effective 2018)
- [Section 801 of the Food and Drug Administration Amendments Act of 2007](#): Read the official publication of FDAAA 801. (Source: U.S. Government Publishing Office)
- [42 CFR Part 11](#): Read the Final Rule for Clinical Trials Registration and Results Information Submission. (Source: Electronic Code of Federal Regulations)
- [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#): Read the NIH policy that establishes the expectation that all investigators conducting clinical trials funded in whole or in part by NIH will ensure that these trials are registered on ClinicalTrials.gov and that results information for these trials is submitted to ClinicalTrials.gov. (Source: FederalRegister.gov)

Other Selected Reporting Requirements:

- Revised Common Rule: Posting of Informed Consent Forms (ICFs):
 - To increase transparency and facilitate more informative ICFs
 - ClinicalTrials.gov: [Document Upload Information data element](#)
 - [Federal law](#) for all trials subject to the Common Rule (effective 2018)
- [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects](#): Read about the NIH policy to ensure the availability of valid analyses of study results by sex/gender and race and/or ethnicity. (Source: NIH Grants & Funding)
 - ClinicalTrials.gov: [Baseline Characteristics](#) and [Outcome Measures](#) data elements
 - NIH-funded phase III applicable clinical trials (effective 2017)