

Adverse Event Module Resources

Selected References

- Council for International Organizations of Medical Sciences (CIOMS). (2005). Management of safety information from clinical trials: Report of CIOMS Working Group VI. https://cioms.ch/wp-content/uploads/2017/01/Mgment_Safety_Info.pdf
- George, G. C., Barata, P. C., Campbell, A., Chen, A., Cortes, J. E., Hyman, D. M., ... Hong, D. S. (2019). Improving attribution of adverse events in oncology clinical trials. *Cancer treatment reviews*, 76, 33–40. <https://doi.org/10.1016/j.ctrv.2019.04.004>
- IND Safety Reporting, 21 C.F.R. § 312.32 (2023).
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32> .
- Institutional Review Boards, 21 C.F.R. § 56 (2023).
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>.
- International Council on Harmonisation of Technical Requirements for Registrations of Pharmaceuticals for Human Use (2016, November 9). Guidelines for Good Clinical Practice E6(R2). Retrieved from https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
- Investigational Device Exemptions, 21 C.F.R. §. 812 (2023).
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812>
- Investigational New Drug Application, 21 C.F.R. § 312 (2023).
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>
- Investigator Safety Reporting, 21 C.F.R. § 312.64 (2023).
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32>
- Medical Dictionary for Regulatory Activities Maintenance (MedDRA[®]). (n.d.). FAQs. National Cancer Institute (NCI) Cancer Therapy Evaluation Program (2021, April 30). Adverse Events/CTCAE.
https://ctep.cancer.gov/protocolDevelopment/adverse_effects.htm
- National Cancer Institute Cancer Therapy Evaluation Program. (2021, April 30). Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS).
http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm
- National Cancer Institute (NCI) Cancer Therapy Evaluation Program. (2017). Common terminology criteria for adverse events (CTCAE) (v5.0).
https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf

National Cancer Institute Cancer Therapy Evaluation Program. (2013, September 16). NCI guidelines for investigators: Adverse event reporting requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs. Retrieved from

https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf

National Cancer Institute (NCI) Division of Cancer Control & Population Sciences (DCCPS) (2024, April 19). Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®). <https://healthcaresdelivery.cancer.gov/pro-ctcae/>

Office for Human Research Protections. (2007, January 15). Reviewing and reporting unanticipated problems involving risks to subjects or others and adverse events.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>

Protection of Human Subjects, 45 C.F.R. § 46 (2018). <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46> <http://www.meddra.org/faq>

U.S. Food and Drug Administration. (2007, September). *Guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical trials.*

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm091977.pdf>

U.S. Food and Drug Administration. (2009, January). *Guidance for clinical investigators, sponsors, and IRBs: Adverse event reporting to IRBs—Improving human subject protection.*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/adverse-event-reporting-irbs-improving-human-subject-protection>

U.S. Food and Drug Administration. (2009, December). *Guidance for industry: Patient-reported outcome measures: Use in medical product development to support labeling claims.*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims>

U.S. Food and Drug Administration (FDA). (2012). *Guidance for industry and investigators: Safety reporting requirements for INDs and BA/BE studies.*

<https://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf>