

ROADMAP TO 2030 FOR NEW DRUG EVALUATION IN OLDER ADULTS

WORKSHOP REFERENCES

U.S FOOD AND DRUG ADMINISTRATION (FDA) AND INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) REFERENCES

The most recent version of these Guidance Documents can be found here:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

- 1989 FDA Guidance for Industry: Guideline for the Study of Drugs Likely to Be Used in the Elderly. 1989.
- 1994 ICH Technical Requirements for Registration of Pharmaceuticals for Human Use: ICH E7: Guideline for Industry: Studies in Support the of Special Populations: Geriatrics. 1994.
- 2000 ICH: E11 Clinical Investigation of Medicinal Products in the Pediatric Population.
- 2005 FDA Guidance for Industry: How to Comply with the Pediatric Research Equity Act.
- 2010 ICH topic E7 Studies in Support of Special Populations: Geriatrics Questions and Answers. 2010. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-7-studies-support-special-populations-geriatrics-questions-answers-step-5_en.pdf
- 2013 FDA Report: Collection, analysis, and availability of demographic subgroup data for FDA-approved medical products. 2013. <https://www.fda.gov/media/86561/download>
- 2014 FDA report: FDA action plan to enhance the collection and availability of demographic subgroup data. 2014. <https://www.fda.gov/media/89307/download>
- 2015 Drug Trials Snapshots Website. 2015 onward. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>
- 2019 FDA Guidance for Industry: Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials.
- 2020 FDA Guidance for Industry: Enhancing the Diversity of Clinical Trial Populations-- Eligibility Criteria, Enrollment Practices, and Trial Designs.
- 2020 FDA Guidance for Industry: Inclusion of Older Adults in Cancer Clinical Trials.
- 2020 FDA Guidance for Industry: Geriatric Information in Human Prescription Drug and Biological Product Labeling.

OTHER REFERENCES

- 1987 Institute of Medicine Report: Pharmacokinetics and Drug Interactions in the Elderly and Special Issues in Elderly African-American Populations: Workshop Summary. 1987. <http://www.nap.edu/catalog/5854.html>
- 2020 National Academy Science Education and Medicine: Drug Research and Development for Older Adult Populations. 2020. <https://www.nationalacademies.org/event/08-05-2020/drug-research-and-development-for-older-adult-populations-a-workshop>
- 2020 National Institutes of Health: Inclusion Across the Lifespan Policy Website. <https://grants.nih.gov/policy/inclusion/lifespan.htm>
- 2021 Research Centers Collaborative Network Workshop: Inclusion of Older Adults in Clinical Research. <https://www.afar.org/events/rccn-event-inclusion-of-older-adults-in-clinical-research>