



National Institutes of Health
National Cancer Institute

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MEMORANDUM

DATE: December 17, 2021

TO: Principal Investigators and Operations/Statistics Offices of NCI National Clinical Trials Network (NCTN) and the Experimental Therapeutics Clinical Trials Network (ETCTN), FDA colleagues, and Industry Collaborators

FROM: Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI

SUBJECT: Modernizing and Broadening Eligibility Criteria Initiative

The NCI Cancer Therapy Evaluation Program (CTEP) would like to emphasize its continued commitment to broadening eligibility criteria (EC) in clinical trials throughout protocol development in collaboration with investigators, industry partners, the U.S. Food and Drug Administration (FDA), ETCTN lead protocol organizations (LPOs) and NCTN Groups. NCI aims to maximize opportunities for diverse populations to participate in cancer research and to have representative samples in NCI clinical trials; therefore, we are announcing an initiative to conduct focused reviews on EC to further expand inclusiveness in NCTN and ETCTN trials.

The American Society of Clinical Oncology (ASCO) and Friends of Cancer Research (Friends) published recommendations in October 2017 to broaden clinical trial eligibility relating to brain metastases, minimum age, HIV infection, organ dysfunction, and prior and concurrent malignancies (Kim, ES, et al. J Clin Oncol 2017, [PMID: 28968170](#)). The FDA offered similar support and guidance in articles published in 2017 and 2020 on re-evaluating eligibility criteria and enhancing diversity in clinical trial populations (Beaver, JA, et al. N Engl J Med 2017, [PMID: 28423289](#); FDA.gov 2020, [Docket Number: FDA-2019-D-1264](#)). CTEP together with input from pharmacology experts on the NCI's Investigational Drug Steering Committee and NCI experts, developed protocol template language from many of these recommendations into its [Generic Protocol Template](#), utilized by the ETCTN. In September 2018, CTEP expected ETCTN LPOs and NCTN Groups to include EC template language to broaden eligibility criteria that lead to some expansion in EC.

In May 2021, ASCO/Friends published additional recommendations to broaden eligibility criteria relevant to washout periods, concomitant medications, prior therapies, laboratory reference ranges, and performance status (Kim, ES, et al. Clin Cancer Res. 2021, [PMID: 33563632](#)), and this additional guidance is included in CTEP's modernized eligibility criteria guidance document, which provides an overview of NCI guidance and preferred protocol text. NCI's expectation is that the ETCTN and NCTN will utilize these modernized eligibility criteria in clinical trials going forward and modify active trials when feasible. Since eligibility criteria must be as broad as safely possible to achieve diverse and representative populations in future clinical trials, CTEP will continue to collaborate with investigators, ETCTN LPOs, NCTN Groups, and industry partners in a shared responsibility to expand eligibility and access to trials.

Thank you for your continued collaboration in this important initiative and documents to support this initiative are at: https://ctep.cancer.gov/protocolDevelopment/templates_applications.htm

For questions or concerns, please contact us at: NCICTEPComments@mail.nih.gov