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Commenting on draft FDA guidance

by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

The U.S. Food and Drug Administration (FDA) establishes rules by drafting, modifying, and publishing through draft guidance. "By law, anyone can participate in the rule-making process by commenting in writing. FDA routinely allows plenty of time for public input (typically 60 days) and carefully considers these comments when it draws up a final rule. The public can submit comments about the proposed regulation directly to the agency (through the mail or online at www.regulations.gov)."[1]

Recently, the FDA asked for Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products. With a deadline in early May, the draft guidance document provided recommendations for the design and conduct of externally controlled trials, including discussions on the validity of a trial without bias.