Position on Use of SI Units for Lab Tests

CDER and CBER are evaluating an approach to transition to general acceptance of laboratory data in clinical trials that are measured and reported in Système International (SI) units instead of U.S. Conventional units. The objective is to establish an agency-wide policy on the acceptance of SI units in product submissions.

CDER and CBER recognize that SI units are the worldwide standard and international trials regularly measure and report lab tests using SI units. The Centers also acknowledge that the majority of U.S. healthcare providers are trained using U.S. conventional units. Lab results reported using U.S. conventional units often convey the most clinical meaning to U.S. healthcare providers, including CDER and CBER reviewers. In the absence of a holistic transition within the U.S. healthcare community to SI units, conversion of certain lab test results to U.S. conventional units may be a necessary interim step toward a transition to full SI unit reporting.

CDER and CBER are currently evaluating common and therapeutic area-specific lab tests to determine which pose significant interpretation risks during the review of new drug applications. While this evaluation is underway, sponsors are strongly encouraged to solicit input from review divisions as early in the development cycle as possible to minimize the potential for conversion needs during NDA/BLA review. CDER and CBER encourage sponsors to discuss this issue with FDA before the start of Phase 3 trials. In some cases the issue may warrant discussion with FDA at the End-of-Phase 2 meeting.

If conversion requests are received, sponsors are advised to discuss the conversion request as early as possible with the review division and if needed, provide a proposal for what can be reasonably accomplished to meet the review division's needs without undue burden in time or costs.

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