International Alliance for Biological Standardization

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Summary of outcomes and key messages from previous GHS meetings: Meeting the challenge of clinically relevant specifications

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Using a scientific basis for setting and maintaining specifications can provide major benefits to patients, regulators, and developers. A clinically relevant (or patient-centric) definition of quality is used to assure that specifications are connected to product quality. Various data sources can inform the definition of quality, including clinical studies, preclinical studies, and prior information. Once quality has been defined, it is possible to select the broadest range of specifications (accounting for assay variability and stability) that are consistent with quality. Alternatively, a similar approach may be used to assure that any desired specification range is consistent with the definition of quality. Critically, specifications should not be used to monitor post-licensure process variability, which is more reliably and appropriately monitored by other elements of the integrated control strategy. Indeed, manufacturing process knowledge may contribute more to an understanding of product quality than individual test results, which are subject to assay variability. By maintaining clinical relevance as the driver for specification development, it is possible to improve international harmonization and outcomes for all stakeholders