

TITLE: Bayesian statistical methods for evaluating interchangeability of clinical samples with non-clinical samples in evaluating measurement procedure and diagnostic test accuracy

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ABSTRACT:

Clinical evaluation of medical device measurement procedures and diagnostic tests may be hampered by difficulty to obtain human clinical samples or images. Non-clinical samples, e.g., animal samples, contrived samples (e.g., from cell line derived DNA), in silico images (Badano, *Trials* 2021), and digital twins, have been proposed as substitutes for clinical samples. Thus, interchangeability of clinical and non-clinical samples, also known as commutability, is important to assess. Interchangeability, commutability, and exchangeability appear to be synonymous terms. We will explore metrics for assessing interchangeability of clinical and non-clinical samples and Bayesian approaches for assessing these metrics. We will also consider combining clinical and non-clinical samples with flexible Bayesian hierarchical models.