Basel Biometric Society Suisse Romande
Webinar Series 2026

Getting the Size Right: finite-sample corrections for univariate & multivariate bioequivalence testing

Date: November 13th, 2026
Time: 14:00-15:00 CET (8:00-9:00 EST)

Venue: Virtual

Speaker:	Younes Boulaguiem (Roche)
Costs per person:	Free

Abstract
Bioequivalence studies seek to demonstrate that a test and a reference product yield responses within predefined equivalence limits. The Two One-Sided Tests (TOST) procedure, the regulatory standard, is simple to apply but conservative in finite samples: its type I error can fall well below the nominal level, particularly for highly variable drugs, small samples or multiple endpoints. The ensuing loss of power translates into larger, costlier studies, or into a failure to establish equivalence that genuinely holds.

This talk presents a unified line of research addressing this shortcoming. The α-TOST recalibrates the significance level of TOST so that its type I error matches the nominal level exactly, yielding a uniformly more powerful test that remains straightforward to compute. Its multivariate extension accounts for the dependence between outcomes when equivalence must be established jointly, and relies on an efficient iterative algorithm. Finally, for locally acting drugs such as topical formulations, where multivariate measurements, small samples and substantial experimental noise are common, a dedicated framework adjusts both the significance level and the equivalence margins, preserving the nominal size while improving power.

The methods are illustrated through case studies on topical antifungal formulations and ticlopidine hydrochloride, and are implemented in the open-source R package cTOST.

Learn more about the speaker!
Younes Boulaguiem is a Statistician in Roche's translational and exploratory biomarker team in Basel, with a current focus on haemophilia and neurology. Prior to joining Roche, Younes was a postdoctoral researcher at the Clinical Research Center of the Geneva University Hospitals (HUG), leading multi-study meta-analyses of survival data across European clinical registries and contributing to longitudinal research on early predictors of Alzheimer's disease. Younes holds a PhD in Statistics from the University of Geneva with research spanning equivalence testing, generative AI models for spatial extremes and simulation-based privacy-preserving inference.

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