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An RShiny Application to guide the Planning and Evaluation of an Analytical Method Transfer

The planning and evaluation of an analytical method transfer is inherently a statistical procedure. However, the whole process of the transfer is the responsibility of the subject matter experts (SMEs). Since only faced irregularly with a method transfer, SMEs usually lack experience or at least regular training in statistical study planning. On the other hand, in view of the usually huge number of analytical methods to transfer and the necessary subject matter knowledge, the statistical part cannot be performed solely by the statistician.

Thus, we developed a training concept that teaches the SME every step from data acquisition over planning and finally evaluation of an analytical method transfer. The hands-on work of an SME is supported by an RShiny application that guides the SME from the evaluation of the data, over setting risk-based acceptance criteria, computing the necessary number of transfer measurements as well as evaluating/visualizing the final result. This working scheme enabled the SMEs to fulfill their task more confidently and independently while still being in contact with statisticians. This led to an increase in efficiency as well as in quality of the transfers.

We would like to present the statistical background as well as the flow of the app. We hope to show what is possible by the enablement of SMEs with proper statistical consultation and would like to open the discussion with the CMC community how in general the usage of self developed statistical apps is seen/judged.

