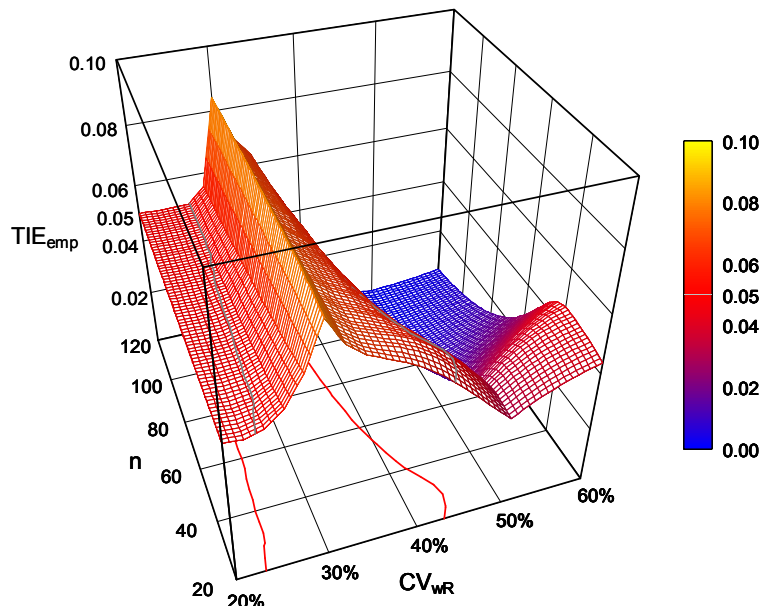


Type I Error (nominal α 0.05)

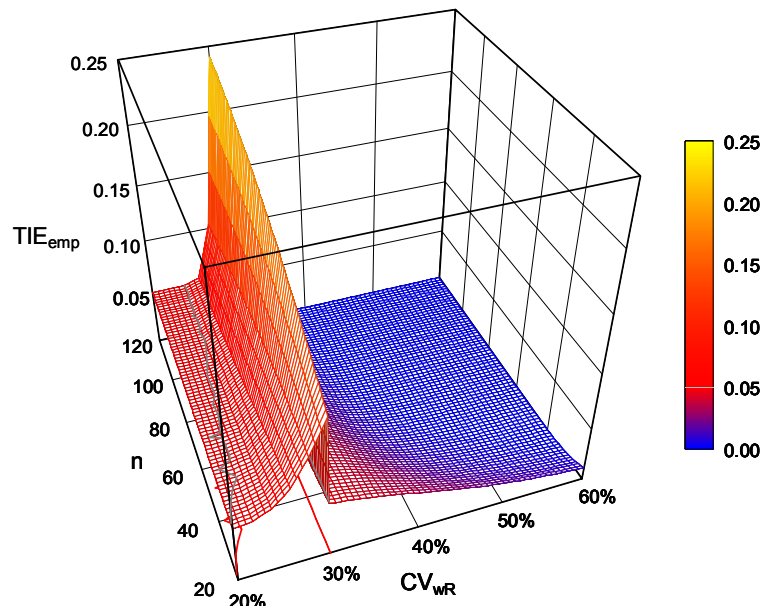
Since in reference-scaling BE-limits are *random variables*, the patient's risk might be compromised

- Example: 4-period 2-sequence full replicate design

ABEL (EMA)



RSABE (FDA)



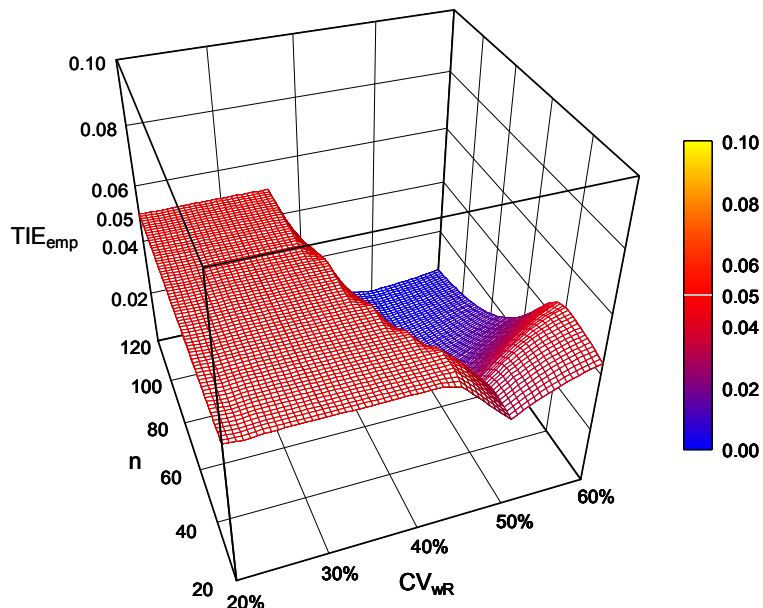
Type I Error (iteratively adjusted α)

Proposed alternative:

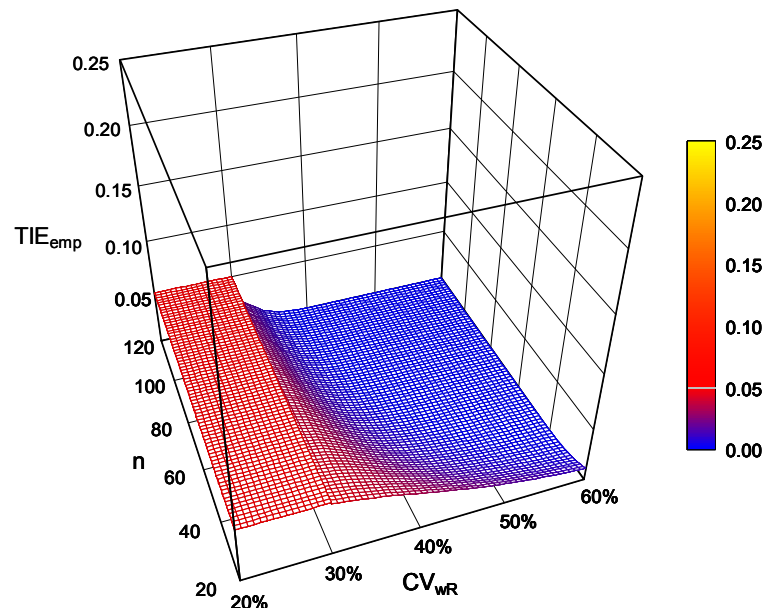
Decreasing the level of the test in the critical region (CV_{wR} , n)

- Example cont'd

ABEL (EMA)



RSABE (FDA)



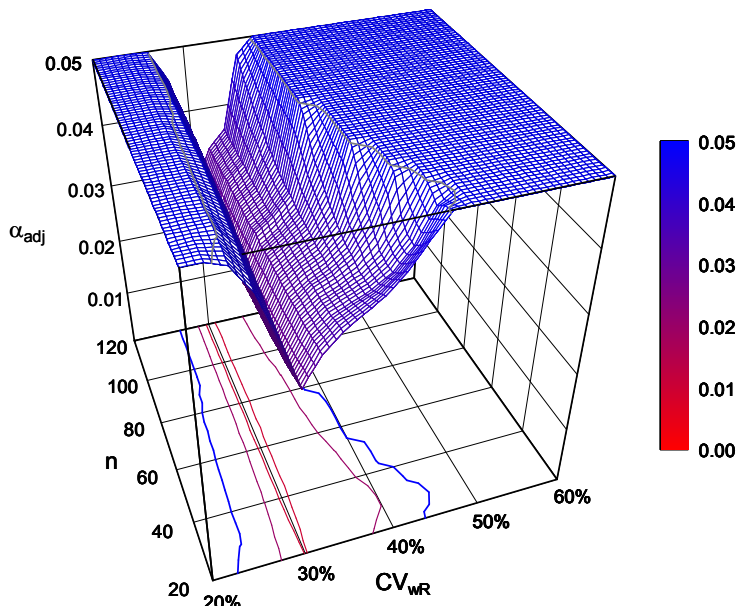
Backup slide (iteratively adjusted α)

Proposed alternative:

Decreasing the level of the test in the critical region (CV_{wR} , n)

- Example cont'd

ABEL (EMA)



RSABE (FDA)

