Title:

Upcycling development data using Bayesian statistics to save experimental resources

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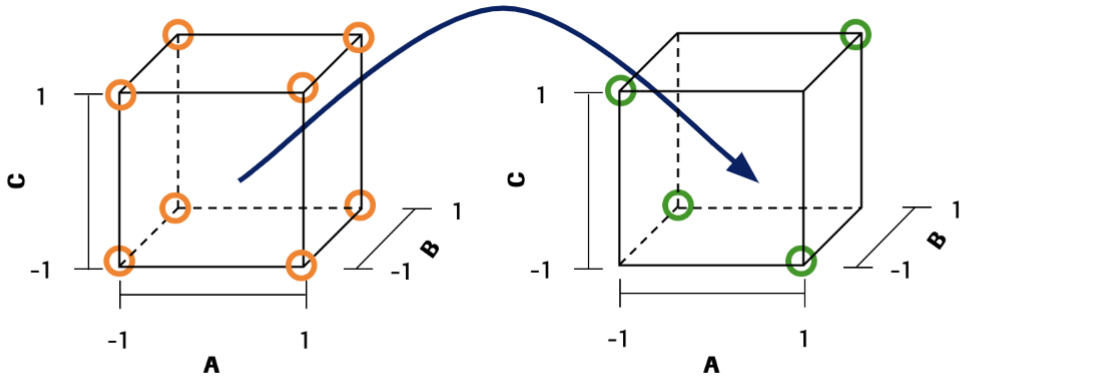
Short Summary / Abstract:

Throughout clinical development of a new drug, changes in the dose strengths are quite common and also occurred in a recent synthetic molecule Drug Product (DP) project. We had fully developed a DP process, then the clinical team requested an additional tablet with a 75% higher dose strength.

The question is: How to make best use of prior knowledge by using the valuable experimental data from the existing DP process to save development efforts for the new DP process? To leverage historical data, we explored the benefits and limitations of the Bayesian framework to use data from established dose strengths for eliciting priors. Preliminary results in our specific use case are very promising: The higher dose strength DP might be developed with 7 experimental batches instead of 11 batches, saving 36% of experimental resources thanks to a highly robust process, accurate analytical methods, a highly consistent process for the old and new dose strength – and Bayesian statistics. Is this too good to be true?



Old dose strength **4 mg**
Full Factorial, n = 8 + 3 = 11 runs

New dose strength **7 mg**
Fractional Factorial, n = 4 + 3 = 7 runs