

Universal Study Design for Instrument Updates in Pharmaceutical Release Analytics

Benchmark: From ICE3 to Maurice

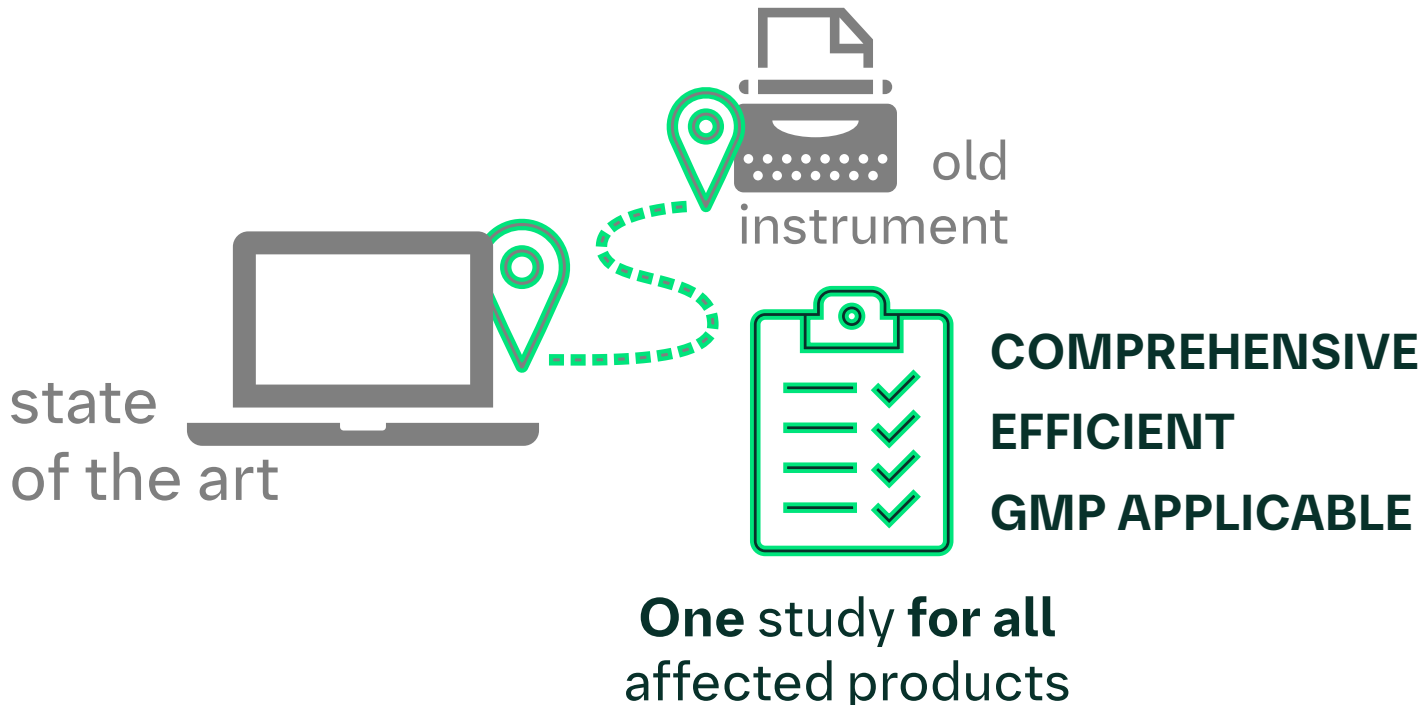


Comparability study

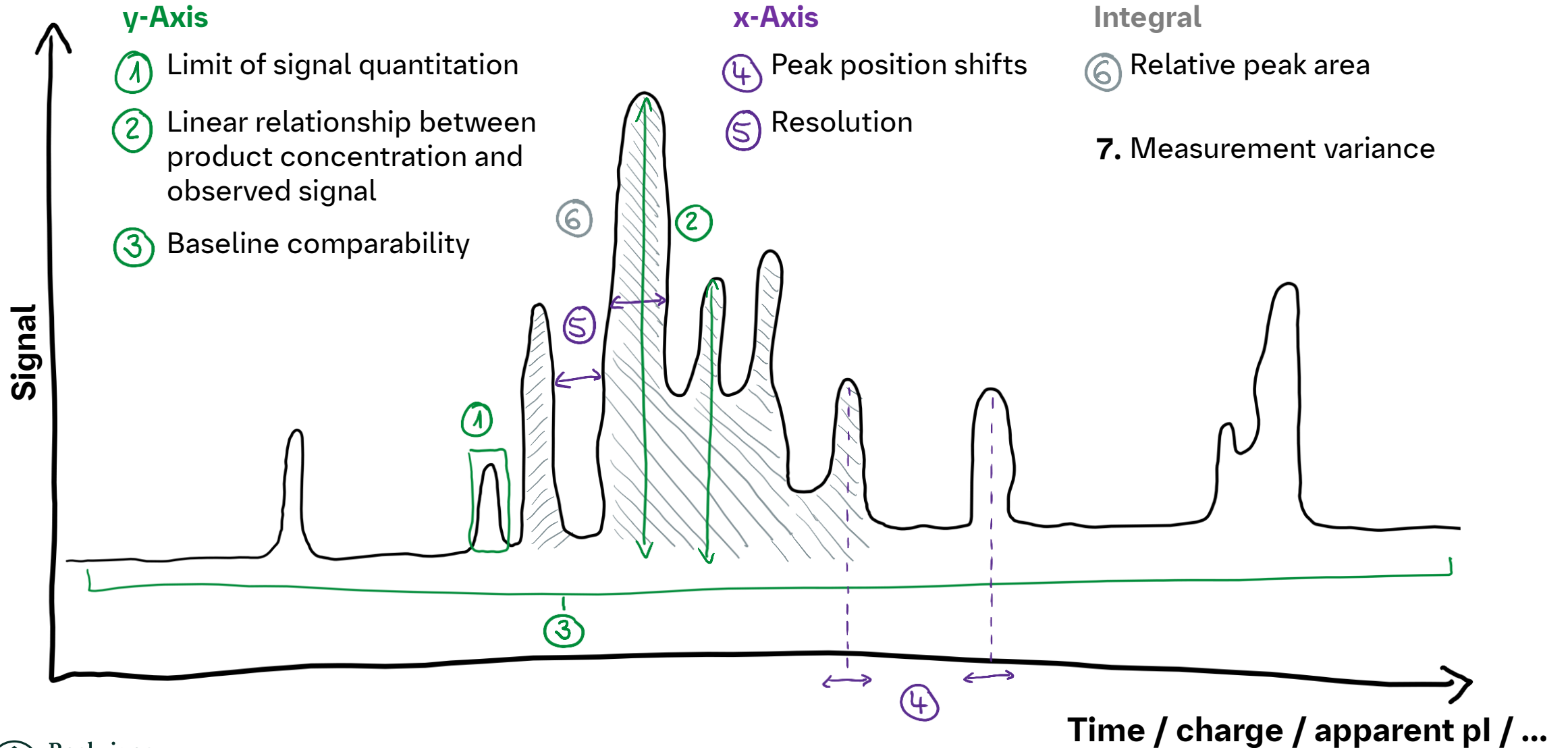
What?

Why?

- Assess potential performance differences
- Rationalize risk assessment / path forward
- Scientific basis for bridging or further targeted (partial) re-validation experiments



Study design

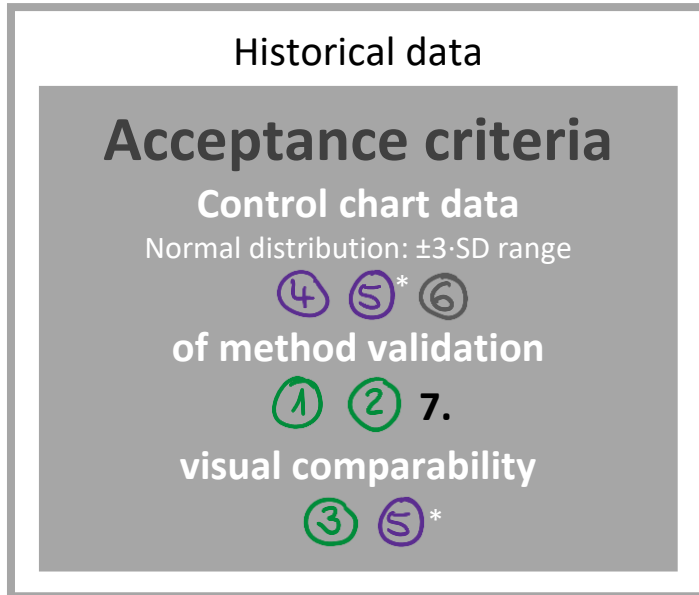


Experimental design

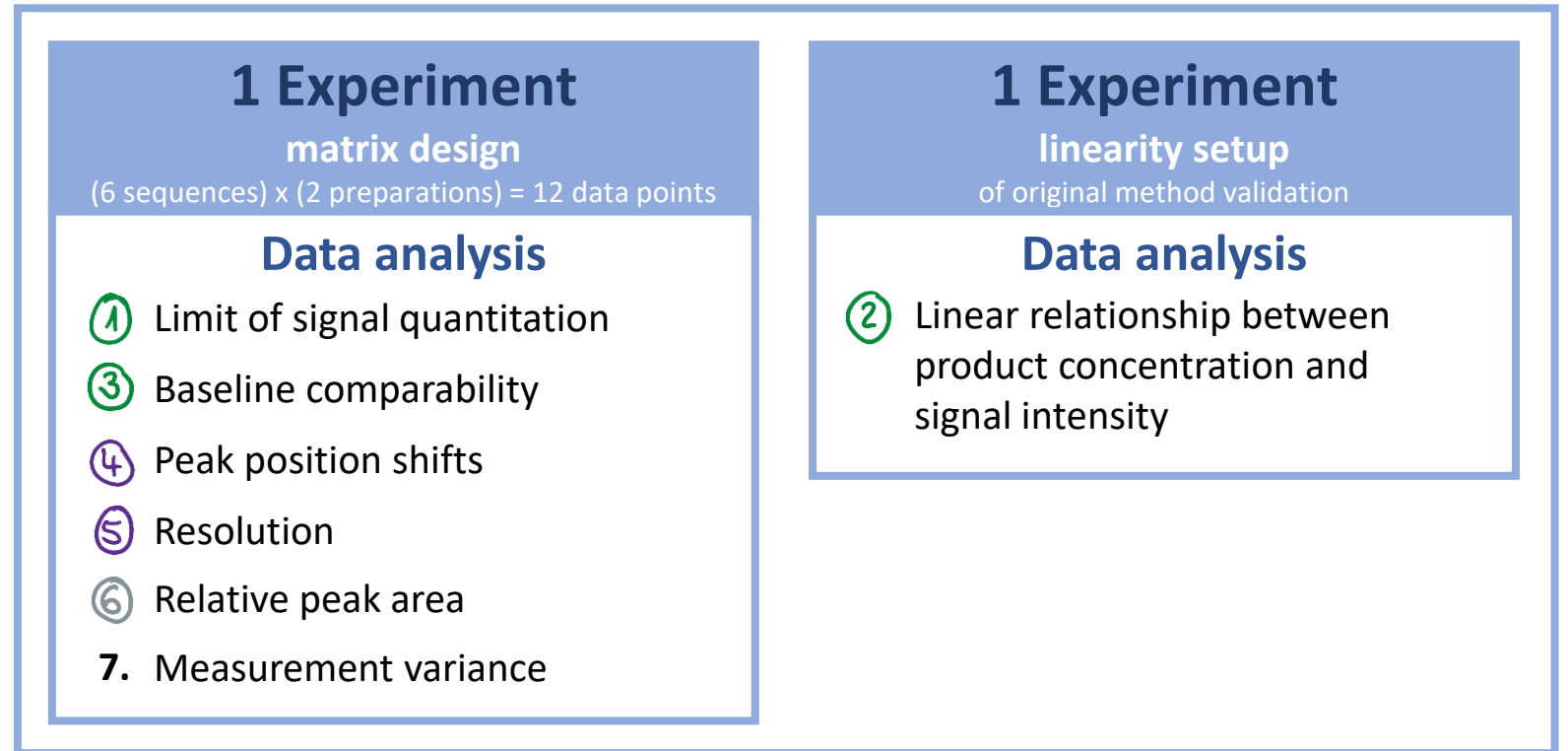
material

Reference material of product with most complex readout / sample preparation

old instrument



new instrument



Benchmark ICE3 → Maurice – Study results

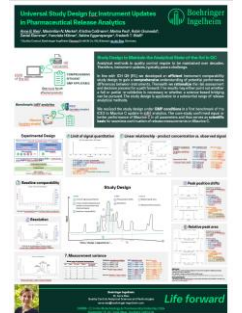


- ① Limit of signal quantitation (LoQ) ✓
- ② Linear relationship – product concentration vs. observed signal ✓
- ③ Baseline comparability ✓
- ④ Peak position shifts ✓
- ⑤ Resolution ✓
- ⑥ Relative peak area ✓
- 7. Measurement variance ✓

Scientific base for seamless continuation of release analytics on Maurice

For more detailed results

- Visit me at my poster :)
- Ries, AB et al. - *Universal Study Design for Instrument Updates in Release Analytics* manuscript under preparation



Everyone involved, especially

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Thank you!