

Assay sensitivity

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FDA

Properties of the control

- Reproducible
- Peak effect ~ signal of interest
 - Evidenced by lower bound $>$ half that
- Time course characterized
 - Less formally assessed

Use in a study

- Similar resolving power to that applied to study drug (fair comparison)
 - Time from baseline
 - Sample size

Alternatives?

- Physiological maneuvers
 - Variability?
 - Confounding with hysteresis?
- Recording properties
 - Experience?