

2017 IABS Statistics Workshop

Meeting Summary

- Common themes

- Nonclinical statisticians should embrace **Bayesian statistics** to address “small dataset” problems and provide scientists with appropriate metrics in formulating decisions during development and commercial manufacture – **prior knowledge**
- **“Big data”** should be a future focus for nonclinical statisticians
- Difficulties in defining **acceptance criteria** needs to be addressed – statistics or SME/clinical – or both
- There’s a need for developing **clinically relevant specifications** –current practice of a few clinical lots with a small range is inadequate – we need strategic solutions, including shelf life and in use
- Nonclinical statisticians should focus carefully on **the question** to support effective design, analysis and decisions
- The effects of **special cause** as well as **common cause variability** should be considered in describing and monitoring process performance
- A requirement for the effective application of nonclinical statistics is **communication** – statisticians with scientists, industry with regulators . . . and statisticians with statisticians
- “There are no wrong notes, some are just more right than others.” More appropriate **models** should be used or developed to “get in tune” with the rest of the biopharmaceutical orchestra (especially on the xylophone).
- Nonclinical statisticians are **decision scientists**. We work best in collaboration with bench scientists, engineers, regulatory scientists and biopharmaceutical leadership in ensuring adherence to the scientific method, and developing robust manufacturing processes which deliver safe and effective products to patients in need