

ClinBAY

Statistical solutions to drug development



Statistical Partner in Early Phase

- ◆ Strong experience in early phase.
- ◆ First in man, PK studies, biomarkers, proof of concept, PK/PD, phase II trials.
- ◆ Flexible services from single trial to whole development plan support.

Adaptive design

- ◆ Decimaker™: Software for adaptive design and Bayesian decision analysis.
- ◆ CRM, D-optimal, NDLM, seamless methods.
- ◆ Dose selection, sample size re-adjustment, early stopping rules.



www.decimaker.com

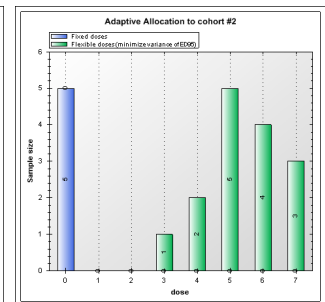
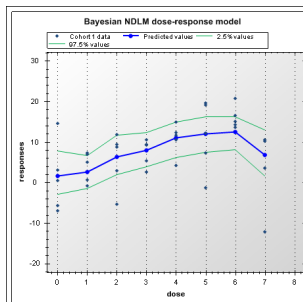
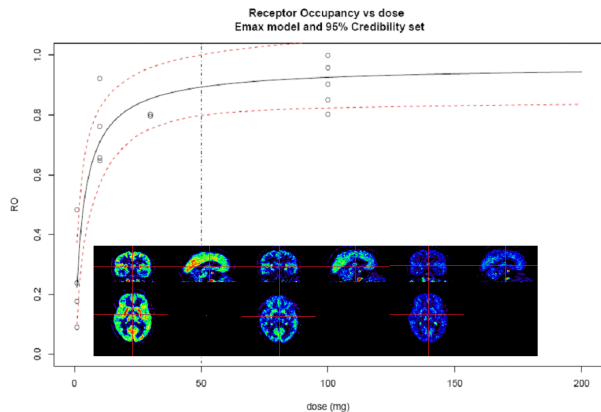
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Clinical Trial Statistics

- ◆ Sample size, protocol development, SAP.
- ◆ Randomisation, minimization methods.
- ◆ Parallel, cross-over, sequential trials.
- ◆ Analyses with SAS, reports based on ICH guidelines.
- ◆ Interim analyses, IDMC, group sequential methods.

Biomarker & Modeling

- ◆ Biomarker trial design & validation: brain imaging, -omics, disease models.
- ◆ PK/PD modeling and predictions.
- ◆ Trial simulations.
- ◆ Bayesian hierarchical models.



Statistical Innovations

- ◆ Investment in methodological research.
- ◆ Partnership with key leaders & universities.
- ◆ Statistical computing & software development.
- ◆ Presentations at conferences, peer-reviewed publications.

MORE INFORMATION



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