
Catherine Duval

Principal Biostatistician

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Summary

Principal Biostatistician with 11 years in clinical development and a PhD in Biostatistics, leading statistics for neurology and rare disease programs. Sets clinical trial design strategy, including adaptive designs and Bayesian methods, represents biostatistics at FDA meetings, and leads 4 statisticians and 5 programmers on statistical analysis in SAS and R.

Experience

Principal Biostatistician

Kendall Point Neurosciences — Cambridge, MA — 03/2021 - Present

Clinical-stage biotech with 5 neurology and rare disease programs.

- Lead biostatistics for 2 programs, including a 900-patient adaptive Phase III in ALS.
- Design Bayesian borrowing and adaptive dose selection plans accepted at 3 FDA Type B and C meetings.
- Direct a team of 4 statisticians and 5 programmers, reviewing SAPs, specifications and key outputs.
- Author statistical sections of an NDA, including the integrated summary of efficacy and 40 FDA query responses.

Senior Biostatistician

Longwood Clinical Statistics — Boston, MA — 06/2017 - 02/2021

CRO biostatistics group serving neurology and immunology sponsors.

- Led statistics on 9 Phase I-III trials in neurology and immunology for 6 sponsors.
- Ran statistical analysis with mixed models and multiple imputation for 3 pivotal readouts.
- Trained 8 junior statisticians on estimands and ICH E9(R1) methods.

Biostatistician

Merrimack Valley Research Institute — Lowell, MA — 09/2015 - 05/2017

- Analyzed 4 investigator-initiated trials and wrote 6 statistical methods sections for journal papers.
- Programmed simulations in R to size 5 grant-funded studies.
- Reviewed data management plans and edit checks for 4 trials before first patient in.

Education

Doctor of Philosophy

Brown University

Biostatistics

Providence, RI

05/2015

Skills

SAS	—	R	—	Statistical Analysis	—	Clinical Trial Design
Adaptive Designs	—	Bayesian Methods	—	Regulatory Submissions	—	ICH E9
Leadership Skills	—	Problem-Solving				