

Andrew Kowalski

ASSOCIATE DIRECTOR, BIOSTATISTICS

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SUMMARY

Associate Director, Biostatistics with 14 years in clinical development and a PhD in Statistics, leading biostatistics for an oncology and immunology portfolio of 11 trials. Owns clinical trial design, SAP strategy and regulatory interactions, manages 6 statisticians and 3 CRO partners, and keeps SAS and R deliverables on time for 2 global submissions.

SKILLS

Other Skills: Clinical Trial Design, Statistical Analysis Plans, Adaptive Designs, Survival Analysis, Regulatory Strategy, SAS, R, CDISC Standards, Team Leadership, Organizational Skills

EXPERIENCE

Associate Director, Biostatistics

02/2022 - Present

Bayview Biotherapeutics

South San Francisco, CA

Commercial-stage biotech with 2 approved products and 6 programs in development.

- Lead biostatistics for 11 Phase I-III oncology and immunology trials with 4,000 patients enrolled.
- Manage 6 statisticians and 3 CRO partners, setting priorities, reviewing work and running yearly reviews.
- Guide clinical trial design and regulatory strategy for 2 global filings, including an sBLA accepted in 2025.
- Cut biostatistics vendor costs by **\$1.8M** a year by moving 4 studies to in-house SAS and R programming.

Principal Biostatistician

05/2017 - 01/2022

Mission Rock Clinical Sciences

San Francisco, CA

Biotech developing antibody therapies for solid tumors.

- Directed statistics for a 1,100-patient Phase III that supported a 2021 FDA approval.
- Wrote statistical analysis plans with adaptive designs and survival analysis for 7 trials.
- Led the biostatistics side of 6 FDA meetings and drafted 50 query responses.

Biostatistician

09/2012 - 04/2017

Peninsula Statistics Group

Palo Alto, CA

- Analyzed 12 Phase I-II trials and delivered datasets and reports to CDISC standards.
- Built R simulation tools for 20 dose-finding and sample size studies.
- Prepared statistical sections for 8 study protocols and clinical study reports.

EDUCATION

Doctor of Philosophy

06/2012

University of California, Davis

Davis, CA

Statistics