Mohamed Amine Bayar, PhD

Independent Biostatistics Consultant | Oncology & Hematology

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Profile

- PhD-level biostatistics consultant with 13+ years across the full clinical development lifecycle — from Bayesian Phase I dose-escalation through Phase III pivotal design, high-stakes analysis milestones, and regulatory submission.
- A profile combining frontline industry experience (Johnson & Johnson, Novartis), academic research depth (PhD Paris-Saclay · 15+ publications · 1,200+ citations), hands-on ML/AI expertise applied to clinical and genomic data (co-invented patent WO2018002385A1), and advanced programming capabilities (R/Shiny, Python, SAS, SQL, Harvard CS50x certified). Direct FDA and EMA interactions on pivotal trial design and regulatory strategy.
- Core expertise in oncology and hematology (multiple myeloma, CML, solid tumors — 8+ disease areas); methodology and regulatory experience transferable across therapeutic areas.

Technical Expertise

- **Statistical Methodology:** Survival analysis (Cox, competing risks, frailty models); linear, logistic, and mixed-effects models; Bayesian dose-escalation (CRM, BLRM, BOIN); group sequential and adaptive designs (OS monitoring for harm, event-restimation, Efficacy interim analysis); multiple testing procedures; Estimand framework (ICH E9(R1)); sample size calculation; penalized regression (Lasso, Ridge, Elastic Net).
- **Programming — R:** tidyverse, ggplot2, RShiny, RMarkdown; OncoBayes2 for BLRM dose-escalation; rpact & gsDesign for group sequential designs; survival & cmprsk for time-to-event data; automated TFL pipeline development.
- **Programming — Other:** SAS (Base, Stat, Macro), Python, SQL.
- **ML/AI:** Predictive modeling and prognostic signature development; variable selection in high-dimensional genomic spaces; internal and external model validation (cross-validation, bootstrap); co-invented patent applying ML to oncology outcomes (WO2018002385A1).
- **Medical Writing:** SAPs, TFL shells, CSRs, SCS/SCE, briefing documents, health authority responses, IBs.

Work experience

Apr 2026 - Present

Independent Biostatistics Consultant, BioSpark, Remote, France

Provides independent statistical consulting across the full drug development lifecycle, from early-phase design through regulatory submission. Develping expertise at the intersection of classical biostatistics and AI/ML methodologies.

Feb 2023 - Mar 2026
3 years & 2 months

Johnson&Johnson

Principal statistician — Oncology & Hematology, Johnson & Johnson, Remote, France

Trial statistician across four oncology programs (multiple myeloma and NSCLC), spanning statistical design, 10+ high-stakes analysis milestones, and regulatory submission.

- **Analysis delivery (teclistamab, ciltacabtagene autoleucel):** Led statistical delivery of multiple analysis packages — interim analyses, safety snapshots, and primary analyses — across two cutting-edge myeloma programs in Phase II multi-arm settings: teclistamab (BCMA×CD3 bispecific); and ciltacabtagene autoleucel (BCMA-directed CAR-T). Provided CRO statistical oversight on two studies and contributed to onboarding and mentoring of new statisticians joining the team.
- **Statistical design and study conduct (ramantamig):** Served as lead statistician for Phase Ib and Phase III design on a first-in-class BCMA×GPRC5D×CD3 trispecific — including BOIN dose-escalation design and simulation, Phase III event re-estimation, interim efficacy analyses, OS harm monitoring, and direct FDA/EMA interactions from concept through regulatory alignment (EOP2 briefing book submission and governance activities).
- **Regulatory submission (amivantamab):** Contributed to the submission package for amivantamab in NSCLC — extending regulatory experience beyond myeloma.
- Authored Protocols statistical sections, SAPs, TFL shells, CSRs, and regulatory briefing documents; prepared written responses to FDA/EMA health authority queries.

Nov 2019 - Jan 2023
3 years 3 months

Senior principal Statistician — CML Portfolio (Scemblix), Novartis, Paris, FR

- **Phase II statistical delivery (asciminib):** Led full statistical delivery for a 4-arm Phase II study — from SAP development through database lock, primary analysis, and reporting — forming part of the integrated evidence base supporting the approved label.
- **Pediatric regulatory program (PIP/iPSP):** Led statistical methodology for a Phase Ib adult-to-pediatric bridging study developed under the joint EMA/FDA pediatric framework (Paediatric Investigation Plan and initial Pediatric Study Plan) — a mandatory regulatory requirement for novel oncology agents. Implemented Bayesian BLRM dose-escalation using the OncoBayes2 R package, including prior calibration from adult data and simulation to support dose recommendation in a pediatric population.
- **Pharmacometrics rotation (formal secondment):** Completed a 7-month full-time rotation within the Novartis pharmacometrics team — nlmixr R package.

Mar 2013 - Oct 2019
6 years 9 months

Statistician — Solid Tumors, Gustave Roussy Cancer Center, Paris, FR

trial statistician on 7 clinical trials (Phase I to III) and multiple translational research projects, with responsibility for trial delivery, methodological research, and scientific publication.

- **Trial delivery and analysis milestones:** Led statistical activities on named programs including POP, CHIPASTIN, HPVRX, MELIPI RX, PACS04, IGRT-P, and others — spanning breast (TNBC, HR+, metastatic, early), ovarian, melanoma, prostate, and pediatric oncology. Delivered full analysis lifecycles including interim, primary, and final analyses.
- **Translational research & prognostic modeling:** Developed and validated multiple prognostic models across tumor types — including three sarcopenia prognostic models, a risk stratification model in pediatric intracranial ependymoma, and a survival prognostic model in second-line metastatic renal cell carcinoma.
- **Precision medicine & platform trials (SAFIR02, MAPPYACTS):** Substantial contributor to two landmark precision medicine genomic screening platforms — delivering fully automated TFL pipelines for IDMC meetings. PhD research (Part 3) focused on optimal statistical analysis strategies for platform trials such as SAFIR02.
- **Co-invented patented ML pipeline:** Built and validated a genomic prognostic signature for TNBC (Patent WO2018002385A1) — owning the full pipeline from raw gene expression extraction through data normalization (fRMA), cross-platform merging, predictive modeling, and internal/external model validation; published in *Annals of Oncology*.
- **Methodological research & academic output:** Generated 15+ peer-reviewed publications (1,200+ citations) across *Annals of Oncology*, *JCO*, *CCR*, *Statistics in Medicine*; Invited visiting scientist at Mayo Clinic, hosted by Prof. Daniel J. Sargent. Taught biostatistics and public health to undergraduates at Paris Sud University.

Education

Oct 2016 - Nov 2019
3 years 1 months

PhD in Public Health - Major Biostatistics, Paris Saclay University, Paris, FR

- Topic: Long-term evaluation of randomized Phase III clinical trials in oncology with rare diseases and biomarker-based subtypes.
- Developed novel methodology for randomized trials with seamless Phase II/III, platform trials, and interim analysis strategies; and produced 3 first-author publications in *Statistics in Medicine*, *Statistical Methods in Medical Research*, and *Computer Methods and Programs in Biomedicine*.

Sep 2010 - Jun 2013
2 years 10 months

Engineer in Statistics, ESSAI - Université de Carthage, Tunis, TN
Diplôme National d'Ingénieur - Statistique et Analyse de l'Information

Sep 2012 - Oct 2013
1 years 1 months

MSc in Computational Biology, ENIT - Univestité El Manar, Tunis, TN
Diplôme National de Mastère de Recherche - Traitement de l'Info. et Complexité du Vivant