



NORMA GUZMAN-BECERRA

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PROFESSIONAL SUMMARY

Founder & Biostatistician at NGB Biostatistics and Programming Consulting LLC with over 20 years of experience in Biostatistics. Proven track record leading statistical strategy for global clinical development programs (Phases 1–4), regulatory submissions (FDA, EMA, Health Canada, PMDA, TGA), and successful indication approvals (EBVALLO, ADVATE, FEIBA). Expert in protocol design, SAP development, CDISC standards, SAS programming, and cross-functional leadership. Delivers high-impact biostatistical consulting, independent programming/validation, and regulatory support to accelerate clinical development and commercialization.

INDICATION APPROVALS

- EBVALLO, only in the EU in **2022**, <https://www.ema.europa.eu/en/medicines/human/EPAR/ebvallo>
- ADVATE, https://www.shirecontent.com/PI/PDFs/ADVATE_USA_ENG.pdf
- FEIBA, https://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf

EXPERIENCE

June 2026 - Present

FOUNDER AND BIOSTATISTICIAN, NGB Biostatistics and Programming Consulting LLC
Texas, United States of America

Home Based (remote)

- Provide independent biostatistics consulting, SAS programming, TFL generation, and regulatory support to biotech and pharma clients.
- Specialize in protocol and SAP development, sample size calculations, ADaM/SDTM specifications, and independent programming/validation.

June 2025 - February 2026

DIRECTOR, BIOSTATISTICS, Kyverna Therapeutic
5980 Horton St., Emeryville, California, 94608-2045

Home Based (remote)

- Provide guidance as an expert in biostatistics for global clinical development. Create and build biostatistics standard at Kyverna, including short term and long-term planning.
 - Hands-on experience on study design, power calculation, statistical analyses, to generate tables, listings, and figures. Prepare statistical methods and results for study reports and contribute to data interpretation and decision-making processes.
 - Provide guidance on data collection, design, and analysis for global studies. Ensure efficient medical and safety data review and monitoring, including DSMB meetings.
 - Working with the CROs, plan, monitor, and analyze global clinical studies. Coordinate the development and review of statistical aspects of regulatory submissions.
 - Offer biostatistical input for overall clinical development strategies, protocol design, statistical analysis plans, and regulatory interactions. Handle briefing books, submissions, and address requests and positions from regulatory agencies.
 - Prepare clinical study documents for eCTD clinical modules. Familiarity with CDISC standards, IWRS, SDTM, ADaM Specs, and review define documents.
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- Contribute statistical expertise to support development and commercialization strategies, including post hoc analyses and interpretation of results.
- Work closely with global medical, clinical operations, regulatory, and safety teams to ensure efficient execution of global clinical trials.
- Developed and authored Standard Operating Procedures (SOPs) and associated Work Instructions (WIs) in alignment with FDA/EMA regulatory requirements and Good Clinical Practice (GCP) standards.

April 2025 - May 2025

DIRECTOR, BIostatISTICS, Efficacy Consulting Group, Inc.
33 Wood Avenue South Suite 600, Iselin, New Jersey, 08830

Home Based (remote)

Served as Director of Biostatistics on a short-term contract, providing leadership and operational oversight of biostatistics resources. Managed key people functions including talent acquisition, staff development, performance management, project assignments, and day-to-day team leadership.

March 2024 - March 2025

DIRECTOR, BIostatISTICS, Atara Biotherapeutics, Inc,
2380 Conejo Spectrum St., Suite 200, Thousand Oaks, CA 91320

Home Based (remote)

- Provide statistical contributions, statistical review, and quality control of Statistical Analysis Plans (SAPs), Table, Figure, and Listing (TFL) shells, Submission Data File (SDF) specifications (SDTM and ADaM), other key-study related documentation, protocol deviations, Data Quality Review (DQR), and other communications.
- Assist in cross-functional study start-up activities, including but not limited to CRF review, and database specifications review.
- Oversee statistical analyses of individual studies/projects.
- Collaborate with the study programming team for study deliverables.
- Strong familiarity with all Company's policies, SOPs and other controlled documents related to study activities.
- Develop statistical analysis plans, perform exploratory data analysis as necessary and provide data interpretation.
- Provide guidelines and standards for consultants to ensure quality of deliverables.
- Assist with study and systems internal audits and external bodies.
- Participate in other activities and meetings as needed.
- Assume managerial responsibilities as needed.
- Assist VP of Biostatistics and Statistical Programming in general process development.

March 2022 - March 2024

ASSOCIATE DIRECTOR, BIostatISTICS, Atara Biotherapeutics, Inc,
2380 Conejo Spectrum St., Suite 200, Thousand Oaks, CA 91320

Home Based (remote)

- Led biostatistical support as project/trial statistician for multiple clinical development programs and trials.
 - Provided strategic statistical input during protocol development, ensuring robust and feasible study designs.
 - Authored and reviewed statistical sections of study protocols and statistical analysis plans (SAPs).
 - Conducted and oversaw statistical analyses of clinical data, interpreted results, and ensured the validity and defensibility of conclusions.
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- Drove the timely delivery of high-quality statistical deliverables and milestones through effective cross-functional coordination with clinical research, statistical programming, regulatory affairs, data management, and medical writing.
 - Led collaboration with data management and clinical operations to ensure high-quality study conduct, database development, and data collection/cleaning processes.
 - Partnered with statistical programming teams to define and deliver high-quality datasets, tables, listings, and figures (TLFs).
 - Collaborated with medical writers on the development of statistical and integrated clinical/statistical reports and other regulatory submissions.
 - Contributed to the development and implementation of departmental standards, tools, templates, and best practices.

November 2018 - March 2022

SENIOR MANAGER, BIOSTATISTICS, Atara Biotherapeutics, Inc,
2380 Conejo Spectrum St., Suite 200, Thousand Oaks, CA 91320

Home Based (remote)

- Served as project/trial statistician supporting multiple clinical development projects and trials.
- Provided statistical input during protocol development to ensure adequacy and statistical feasibility of proposed study designs.
- Developed statistical sections of study protocols and statistical analysis plans.
- Performed statistical analyses of study data and interpreted results to ensure validity of conclusions.
- Ensured achievement of statistical deliverables and milestones in coordination with cross-functional teams, including clinical research, statistical programming, regulatory affairs, data management, and medical writing.
- Collaborated with data management and clinical operations throughout the trials to provide statistical input on study conduct, database development, and data collection/cleaning.
- Worked with statistical programming to ensure appropriate programs and documentation were developed for dataset creation and output generation.
- Interacted with medical writers in the development of statistical and integrated clinical/statistical reports.
- Contributed to the development of functional-level standards, tools, and templates.

April 2016 - September 2018

PRINCIPAL BIOSTATISTICIAN, PRA Health Sciences,
4130 Park Lake Ave., Raleigh, North Carolina, 27612

Home Based (remote)

- Serve as the lead biostatistician on programs of studies or submissions, or on simple to complex individual studies.
- Develop statistical analysis plans and specifications for simple to complex clinical studies.
- Serve as an independent reporting statistician on data monitoring committees. Reviews of statistical analysis of other statisticians and interprets results from simple to complex clinical studies.
- Perform senior review of TFLs and statistical analysis plans.
- Provides significant input in the development and review of CRFs, edit specifications, and critical variable lists.
- Perform lead review of TFLs and derive datasets for clinical studies.
- Review simple to complex randomization specifications and dummy randomization schemes. Contributes to clinical study protocols and clinical study reports.

March 2015 - April 2016

PRINCIPAL BIOSTATISTICIAN, PAREXEL International



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195 West Street, Waltham, Massachusetts, 02451

Home Based (remote)

- Provide broad statistical support, including trial design, protocol and CRF development on specific studies.
- Lead production and quality control of randomization, analysis plans, statistical reports, statistical sections of integrated clinical reports and other process supporting documents.
- Perform sample-size calculations, generate randomization lists and write statistical methodology sections for Clinical Study inclusion in study protocols.

September 2014 - March 2015

MANAGER BIOSTATISTICS, PROSOFT Clinical Inc.

851 Duportail Road, 2nd Floor, Chesterbrook, Pennsylvania 19087

Home Based (remote)

- Responsible for performing project tasks, communicating with clients, and preparing cost estimates for potential projects.
- Communicate with clinical teams on statistical methods and results.
- Write and/or review protocols, statistical analysis plans and reports.
- Write and/or review Standard Operating procedures (SOPs) and departmental policies and guidelines.

March 2005 - September 2014

SENIOR BIOSTATISTICIAN, Baxter Healthcare Corporation

One Baxter Way, Suite 100, Westlake Village, California, 91362

- Represents biostatistics in regulatory meetings.
- Supports development/review protocols, author statistical analysis plans, and writing analysis for DSMBs/DMCs, PSURs, PBERs, ISSs, ISEs, CSRs, and CTgov.
- Participate in study meetings; keep up-to-date on study issues.
- Main author of programming specifications (tables, figures, and listings) for Clinical Study Reports abstracts, posters, presentations, and manuscripts.
- Interact closely with statistical SAS programmers to review/expedite delivery of SAS output.
- Senior Biostatistician supported two indication approvals globally.

EDUCATION

- M.S. BIOSTATISTICS
 - University of California-Los Angeles
- B.A. MATHEMATICS
 - University of California San Diego
- CLINICAL TRIALS CERTIFICATE
 - University of California San Diego

SKILLS

- Clinical Research
 - Data Analysis
 - Clinical Trials
 - Project Management
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- Protocol Development
 - Regulatory Knowledge
 - Statistical Analysis
 - Team Leadership
 - Regulatory Compliance
 - SAS programming
 - Statistical Modeling
 - Strategy

AFFILIATIONS

American Statistical Association

REFERENCES

References available upon request

LANGUAGES

- **English** Fluent
- **Spanish** Fluent

AWARDS

- Atara Biotherapeutics:
 - Innovation Award, Nov/**2021**
- PRA Health Sciences:
 - Local Knowledge Award, Oct/**2017**
- Baxter Healthcare Corporation:
 - High-Performing Team Award, May/**2014**
 - Project Management Team Award, May/**2013**
 - Corporate Technical Award, Apr/**2013**
 - Distinguished Contribution Award, Apr/**2013**
 - Regulatory approval of ADVATE prophylaxis indication and execute successful launch in the US and Canada, Apr/**2012**
 - Corporate Technical Award, “Customer First”, Jun/**2011**
 - Bioscience Award “Collaboration & Teamwork”, Jun/**2011**
- University of California San Diego:
 - Provost Honors, **1993-1996**
 - Summer Session Scholarships, **1993-1996**

PUBLICATIONS/MANUSCRIPTS/POSTERS

- A Multicenter, Real-World Natural History Study on Timed 25-Foot Walk Outcome Measures in Stiff Person Syndrome. Newsome, S.D., Lowe, M., Afshar, H., Money, K.M., Buyukurt, A., Chen, H.R., Crawford, B., Eggmann, S., Elfasi, A., Filippatou, A., Quesisi, M.M., Riveros, D., Salazar-Camelo, A., Zook, J., **Guzman-Becerra, N.**, Leslie, J., Geherin, S., Piquet, A.L. Poster presented at the American Academy of Neurology (AAN) 78th Annual Meeting, Chicago, IL, April 20, **2026**.



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https://docs.publicnow.com/viewDoc?filename=241290%5CEXT%5CEEAD5A2BFAF6C3BACBFF8BD4E6D437B04FD40943_1E72B050C475915BBAA87A466E008A20C307235F.PDF

- Comparative analysis of tabellecleucel and current treatment in patients with Epstein-Barr virus- positive post-transplant lymphoproliferative disease following hematopoietic cell transplant or solid organ transplant. *Journal of Medical Economics*; **2024**, VOL. 27, NO. 1, 789–795. Authors: Arie Barleva, Heiner Zimmermann, [Norma Guzman-Becerra](#), Aditi Mehta, Baodong Xing, Berengere Macabeo, Marion Thivolet, and M. Alan Brookhart <https://doi.org/10.1080/13696998.2024.2354150>
- Tabellecleucel for allogeneic haematopoietic stem-cell or solid organ transplant recipients with Epstein–Barr virus positive post-transplant lymphoproliferative disease after failure of rituximab or rituximab and chemotherapy (ALLELE): a phase 3, multicenter, open-label trial. *Lancet Oncol* **2024**; 25: 376–87. Authors: Kris Michael Mahadeo, Robert Baiocchi, Amer Beitinjaneh, Sridhar Chaganti, Sylvain Choquet, Daan Dierickx, Rajani Dinavahi, Xinyuan Duan, Laurence Gamelin, Armin Ghobadi, [Norma Guzman-Becerra](#), Manher Joshi, Aditi Mehta, Willis H Navarro, Sarah Nikiforow, Richard J O’Reilly, Ran Reshef, Fiona Ruiz, Tassja Spindler, Susan Prockop [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(23\)00649-6/abstract](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(23)00649-6/abstract)
- Outcomes for patients with EBV-positive PTLD post-allogeneic HCT after failure of rituximab- containing therapy *Bone Marrow Transplantation Journal* 59, 52–58 (**2024**). Authors: Gérard Socié, Pere Barba, Arie Barlev, Jaime Sanz, Irene García-Cadenas, Patrice Chevallier, Franca Fagioli, [Norma Guzman-Becerra](#), Deepali Kumar, Per Ljungman, Arnaud Pigneux, Natalia Sadetsky, Lucrecia Yáñez San Segundo, Mazyar Shadman, Jan Storek, Dhanalakshmi Thirumalai, Baodong Xing & Mohamad Mohty. <https://doi.org/10.1038/s41409-023-02127-9>
- Epstein-Barr virus-specific cytotoxic T lymphocyte precursors (EBV-CTLp) after tabellecleucel correlates with response & survival in rituximab relapsing or refractory EBV posttransplant lymphoproliferative disease (PTLD) *Cytotherapy*, Volume 22, Issue 5, Supplement, May **2020**, Page S135 Authors: S. Prockop, R.R. Shen, [N. Guzman-Becerra](#), Y. Sun, F. Forozan, E. Doubrovina, R.J. O’Reilly, X. Li, M. Hiremath, L. Gamelin, W. Navarro, B.T. Aftab <https://doi.org/10.1016/j.jcyt.2020.03.265>
- Exploring the Impact of Humoral Immunogenicity with Tabellecleucel for the Treatment of EBV+ PTLD Following HCT and SOT Blood (**2022**) 140 (Supplement 1): 7529–7530. Authors: Tassja J Spindler, Fiona Ruiz, Tiffany Jehng, Hanna Ding, [Norma Guzman-Becerra](#), Shahram Khanzadeh, Xiaoming Li, Laurence Gamelin, Jason A. Dubovsky, Cokey Nguyen <https://doi.org/10.1182/blood-2022-157673>
- Correlation of Epstein-Barr virus-specific cytotoxic T lymphocyte precursors (EBV-CTLp) after tabellecleucel with response and survival in rituximab relapsing or refractory EBV+ post-transplant lymphoproliferative disease (PTLD) Meeting Abstract: **2020** ASCO-SITC Clinical Immuno-Oncology Symposium *Journal of Clinical Oncology*. Volume 38, Number 5_suppl Authors: Authors: Blake T. Aftab, Rhine R. Shen, [Norma Guzman-Becerra](#), Yan Sun, Farahnaz Forozan, Susan Prockop, Ekaterina Doubrovina, Richard J. O’Reilly, Xiaoming Li, Minoti Hiremath, Laurence Gamelin, and Willis H. Navarro https://ascopubs.org/doi/10.1200/JCO.2020.38.5_suppl.38
- ADVATE prophylaxis: post hoc analysis of joint bleeding episodes Haemophilia/**2014** John Wiley & Sons Ltd January 9, 2014 Authors: Leonard Valentino, Celine Reyes, Bruce Ewenstein, [Norma Guzmán-Becerra](#), Wing Yen Wong, Claudia Schoenig-Diesing, Vadim V Romanov



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<https://onlinelibrary.wiley.com/doi/10.1111/hae.12382>

- Randomized comparison of prophylaxis and on-demand regimens with FEIBA NF in the treatment of hemophilia A and B with inhibitors Haemophilia/2013 John Wiley & Sons Ltd August 1, **2013** Authors: Sandra V. Antunes, Srilatha Tangada, Oleksandra Stasyshyn, Vasily Mamonov, Julia Phillips, [Norma Guzmán-Becerra](#), Ani Grigorian, Bruce Ewenstein, Wing Yen Wong
<https://onlinelibrary.wiley.com/doi/10.1111/hae.12246>
- Experience of Advate rAHF-PFM in previously untreated patients and minimally treated patients with haemophilia A Thrombosis and Haemostasis/Schattauer April 4, **2012** Authors: Günter Auerswald, Alexis A. Thompson, Michael Recht, Deborah Brown, Raina Liesner, [Norma Guzmán-Becerra](#), Jacqueline Dyck-Jones, Bruce Ewenstein, Brigitt Abbuehl <https://pubmed.ncbi.nlm.nih.gov/22476554/>
- Characteristics of Malt Liquor Beer Drinkers in a Low-Income, Racial Minority Community Sample Alcohol Clinical and Experimental Research, John Wiley & Sons, Inc. March 1, **2005** Authors: Ricky Bluthenthal, Didra Brown Taylor, [Norma Guzmán-Becerra](#), Paul Robinson
<https://pubmed.ncbi.nlm.nih.gov/15770116/>
- A Longitudinal Analysis of Unmet Need for Oral Treatment in a National Sample of Medical HIV Patients American Journal of Public Health/American Public Health Association January **2005** Authors: Marvin Marcus, Carl A. Maida, Ian D. Coulter, James R. Freed, Claudia Der- Martirosian, Honghu Liu, Benjamin Freed, [Norma Guzmán-Becerra](#), Ronald M. Andersen <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2003.025403>
- Do People with HIV Get the Dental Care They Need? RAND Corporation **2005** Authors: Arleen Leibowitz, Ian D. Coulter, Kevin C. Heslin, Marvin Marcus, Ron D. Hays, James Freed, Claudia Der-Martirosian, [Norma Guzmán-Becerra](#), William Cunningham, Ronald Andersen, William R. Maas, Isabel Garcia, Donald A. Schneider, Barbara Genovese, Martin F. Shapiro, Samuel A. Bozzette, Aram Dobalian, Judith Stein, Sally C. Morton, Carl A. Maida, Fariba Younai, Honghu H. Liu, Benjamin A. Freed
https://www.rand.org/pubs/research_briefs/RB9067.html#:~:text=People%20with%20HIV%20Don%27t,not%20receive%20regular%20dental%20care.
- Self-reported Oral Health of Enrollees in Capitated and Fee-for-Service Dental Benefit Plans Journal of the American Dental Association/American Dental Association November **2004** Authors: Ian D. Coulter, John M. Yamamoto, Marvin Marcus, James Freed, Claudia Der- Martirosian, [Norma Guzmán-Becerra](#), L. D. Brown, Albert H. Guay
[https://jada.ada.org/article/S0002-8177\(14\)63255-4/abstract](https://jada.ada.org/article/S0002-8177(14)63255-4/abstract)
- Self-reported satisfaction of enrollees in capitated and fee-for-service dental benefit plans Journal of the American Dental Association/American Dental Association October **2004** Authors: Ian D. Coulter, James Freed, Marvin Marcus, Claudia Der-Martirosian, [Norma Guzmán-Becerra](#), Albert H. Guay, L. D. Brown
[https://jada.ada.org/article/S0002-8177\(14\)64652-3/abstract](https://jada.ada.org/article/S0002-8177(14)64652-3/abstract)
- Oral White Patches in a National Sample of Medical HIV Patients in the Era of HAART Community Dentistry and Oral Epidemiology/Blackwell Munksgaard March **2004** Authors: Marvin Marcus, Carl A. Maida, James R. Freed, Fariba Younai, Ian D. Coulter, Claudia Der-Martirosian, Honghu Liu, Benjamin Freed, [Norma Guzmán-Becerra](#), Martin Shapiro <https://onlinelibrary.wiley.com/doi/10.1111/j.1600-0528.2004.00171.x>



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- Associations of self-reported oral health with physical and mental health in a nationally representative sample of HIV persons receiving medical care Quality of Life Research/Kluwer Academic Publish February **2002** Authors: Ian D. Coulter, Kevin Heslin, Marvin Marcus, Ron D. Hays, James Freed, Claudia Der-Martirosian, **Norma Guzmán-Becerra**, William Cunningham, Ronald Andersen, Martin F. Shapiro
<https://link.springer.com/article/10.1023/A:1014443418737>
 - Self-reported oral dryness and HIV disease in a national sample of patients receiving medical care Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, Endodontology. **2001** Dec;92(6):629-36 December 2001 Authors: Fariba S. Younai, Marvin Marcus, James R. Freed, Ian D. Coulter, William Cunningham MD, Claudia Der-Martirosian, **Norma Guzmán-Becerra**, Martin Shapiro
<https://www.sciencedirect.com/science/article/pii/S1079210401342038>
 - Self-reported Behavior and Attitudes of Enrollees in Capitated and Fee-for-Service Dental Benefit Plans American Dental Association/RAND Corporation **2001** Authors: Ian Coulter, Marvin Marcus, James Freed, Claudia Der-Martirosian, **Norma Guzmán-Becerra**, Barbara Genovese, Dana Goldman
https://www.rand.org/pubs/monograph_reports/MR1213.html