Kuan-Chieh (KC) Huang, Ph.D.

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SUMMARY

- Seasoned biostatistics leader with 15+ years of experience driving statistical strategy and delivering high-impact results across Oncology, Immunology, and Hepatology drug development.
- Proven track record leading global clinical programs from early development through pivotal trials and regulatory submissions (NDA, BLA, sNDA), including interactions with FDA and EMA.
- Strategic partner to Clinical, Regulatory, Clinical Pharmacology, and Commercial functions driving trial design, evidence generation, and data-driven decision-making.
- Experienced in building and scaling biostatistics functions, optimizing processes, and ensuring operational excellence across in-house teams and CROs.
- Recognized for mentoring, fostering high-performing teams, and championing innovative methodologies that enhance efficiency and regulatory readiness.

WORK EXPERIENCE

Candid Therapeutics – San Diego, CA, USA Jan 2026 - Present

Executive Director, Head of Data and Statistical Sciences (DSS)

- Serve as the head of DSS (Biostatistics and Statistical Programming) and led clinical development programs from first-in-human through Phase 2, ensuring scientifically rigorous, regulator-ready study designs.
- Lead clinical trial design and statistical strategy, including endpoint selection, estimands, sample size determination, interim/adaptive analyses, and decision criteria for go/ no-go milestones.
- Own regulatory biostatistics across Pre-IND/IND/CTA, End-of-Phase meetings, and NDA/BLA-enabling packages; authored and reviewed protocols, SAPs, CSRs, and statistical sections of regulatory submissions.
- Act as primary statistical representative to FDA/EMA, supporting regulatory interactions, briefing documents, and responses to agency questions.
- Direct hands-on analyses and critical ad-hoc data reviews to inform executive, board, and investor decisions under tight timelines and incomplete data.
- Build and lead the biostatistics and statistical programming function in a lean environment, defining standards, workflows, and quality expectations while balancing in-house execution and CRO outsourcing.
- Select, manage, and oversee CROs and external vendors, ensuring on-time, high-quality delivery of datasets, TFLs, and analyses; intervened as needed to de-risk key deliverables.
- Partner cross-functionally with Clinical, Regulatory, Clinical Pharmacology, Data Management, and Program Management to align statistical strategy with overall development objectives.
- Translate complex statistical results into clear, decision-focused narratives for senior leadership, Board of Directors, and external partners.
- Support business development and due diligence activities by assessing data robustness, development risk, and probability of technical success.

Eli Lilly and Company (via DICE Acquisition) Jan 2024 – Jan 2026

Senior Director, Statistics, Immunology

- Provided continued leadership for the DICE Data & Statistical Sciences (DSS) group post-acquisition, ensuring organizational continuity, integration with Lilly standards, and delivery excellence.
- Directed statistical strategy and delivery for DC-806 and DC-853 Phase 2 proof-of-concept studies, influencing go/no-go decisions and Phase 3 readiness.
- Approved and ensure quality of protocols, SAPs, CSRs, and publications, maintaining consistency across CRO-delivered outputs.

- Guided statistical oversight for Phase 3-enabling Clinical Pharmacology studies, partnering with Clinical Pharmacology, Clinical Science, and Drug Safety.
- Maintained operational harmonization with Lilly standards while preserving scientific rigor and team agility.

DICE Therapeutics, Inc – South San Francisco, CA, USA July 2022 – Jan 2024
Director, Data & Statistical Sciences, Immunology
- Established and led the DSS department, including Biostatistics and Statistical Programming, building organizational structure, processes, and SOPs to support pipeline growth and submission readiness.
- Led statistical design and analysis for DC-806 Phase 1 and 2 trials, delivering topline data that informed key investment and regulatory strategies.
- Acted as a strategic advisor to executive leadership and cross-functional teams on clinical trial design, regulatory planning, and risk mitigation.

Genentech, Inc – South San Francisco, CA, USA Aug 2017 – Jul 2022
Principal Statistical Scientist, Data & Statistical Sciences, Oncology
- Led statistical strategy for **ipatasertib** (breast/prostate) and **tiragolumab** (breast/gynecologic) programs, shaping clinical development plans, integrated evidence strategies, and pivotal trial designs.
- Represented Data Science in global development and lifecycle teams, ensuring statistical alignment with clinical, regulatory, and commercial objectives.
- Partnered with regulatory and clinical functions on filing strategies, represented biostatistics in FDA Type B meetings, and served as statistical lead in FDA/EMA interactions.
- Pioneered innovative trial designs (surrogate endpoints, adaptive approaches) that accelerated development timelines.
- Spearheaded enterprise-wide initiatives (surrogate endpoint validation, PFS audit processes, dummy unblinding) to strengthen data credibility for regulatory submissions.

Gilead Sciences, Inc - Foster City, CA, USA January 2015 – August 2017
Senior Biostatistician, Biostatistics, Liver Disease
- Lead statistician for pivotal Phase 3 studies supporting approval of **Epclusa® (SOF/VEL)** and **SOF/VEL/VOX**; authored SAPs and supported NDA/sNDA submissions.
- Directed statistical analyses for Integrated Summary of Safety (ISS) across multiple global studies.
- Collaborated with cross-functional teams (Regulatory, Clinical Research, Operations, Programming) to ensure high-quality data delivery for filings and publications.
- Introduced Bayesian dose-finding methods in oncology and mentored junior statisticians.

Novartis Pharmaceuticals - Cambridge, MA, USA May 2014 – August 2014
Intern in Oncology Translational Medicine
- Created a GUI for Bayesian single and combination dose-finding design, and 3D surface plot for visualizing the posterior DLT rate.
- Evaluated the performance of the standard 5-parameter and the new 7-parameter Bayesian model.
- Re-modeled drug-drug interaction (DDI) in the model for making better suggestion about dose escalation decision.

Amgen Inc. (Onyx Pharmaceuticals) - South San Francisco, CA, USA June 2013 – August 2013
Intern in Department of Biostatistics
- Investigated a Bayesian logistic regression (BLR) approach for combination dose-finding problem.
- Proposed a method for prior distribution selection and 3 dose escalation schemes.
- Proposed a method to determine maximum sample size of the trial.

- Created an R package for BLR combination dose-finding including 3 dose escalation schemes.
- Created a Phase I protocol study design and template language for statistical related sections when BLR method will be employed for dose finding 2-drug combination.

RESEARCH EXPERIENCE

Department of Biostatistics, University of North Carolina, Chapel Hill, USA August 2010 – May 2015

Research Assistant

- Across-platform imputation of DNA methylation levels incorporating nonclinical information using penalized functional regression (Published)
  - Developed the underlying model for DNA methylation prediction.
  - Evaluated imputation quality using 5-fold cross-validation.
  - Proposed under-dispersion measure to filter out the imputed values from under-fitted model.
- Penalized Functional Region-based Test for DNA Methylation (In progress)
  - Applied roughness penalty smoothing and least square smoothing for estimating DNA methylation function.
  - Incorporated B-spline and Fourier basis when estimating DNA methylation function and effect.
  - Investigated type I error and statistical power by treating the DNA methylation effect coefficient as either fixed or random.
- Association Studies with Imputed SNPs Using Expectation-Maximization-Likelihood-Ratio Test. (Published)
  - Proposed new methods that incorporate uncertainty when analyzing imputed genotypes under two scenarios 1) when posterior probabilities of genotypes are estimated or 2) when only imputed dosages are available.
  - Developed an expectation-maximization (EM) likelihood-ratio test (LRT) for association studies when posterior probabilities are estimated.
  - Derived the distribution for sampling the probabilities of all three possible genotypes when dosages are observed only.
- Patterns of Indel Variation in 202 Drug Target Genes From >14,000 Individuals. (In progress)
  - Studied the patterns of insertion and deletion variants (indels) with massively parallel sequencing technologies, such as Dindel, GATK, and novel method developed at BGI.
  - Evaluated indel variations and linkage disequilibrium (LD) patterns within and across populations, and assessed their impact on human traits.
- AbCD: Arbitrary Coverage Design for Sequencing-Based Genetic Studies. (Published)
  - Presented two software tools: ShotGun and DesignPlanner, which were used to generate the estimates behind AbCD.
  - ShotGun plus DesignPlanner can accommodate effective sample size estimate for any combination of high-depth and low-depth, or combination of sequence and genotype data.

Department of Statistics, University of Michigan, Ann Arbor, USA August 2008 – May 2010

Graduate Student Instructor - "Introduction to Statistics and Data Analysis"

PUBLICATION

- Warren, RB, …, Huang KC, …, Lu, TT. Clinical proof of concept for small molecule mediated inhibition of IL-17 in psoriasis. *PLoS One* 21(1): e0341049
- Gutzmer, R., …, **Huang KC**, …, Ascierto PA. Atezolizumab, vemurafenib, and cobimetinib as first-line treatment for unresectable advanced BRAFV600 mutation-positive melanoma (IMspire150): primary analysis of the randomised, double-blind, placebo-controlled, phase 3 trial (vol 395, pg 1835, 2020). *Lancet* 396, no. 10249 (2020): 466-466.
- Lewis, K.D., …, **Huang KC**, …, Manikhas, G.M.

Patient-reported outcomes (PROs) from the phase Ill IMspire150 trial of atezolizumab (A) plus cobimetinib (C) plus vemurafenib (V) in patients (pts) with BRAF (V600+) melanoma. *Journal of Clinical Oncology.* (Vol. 38, No. 15).

- Jotte, R., …, **Huang KC**, …, Socinski M.A.
  Atezolizumab in Combination With Carboplatin and Nab-Paclitaxel in Advanced Squamous NSCLC (IMpower131): Results From a Randomized Phase III Trial. *Journal of Thoracic Oncology*.
- Jottte, R, …, **Huang KC**, …, Socinski M.A.
  IMpower131: Final OS Results of Carboplatin + Nab-Paclitaxel ± Atezolizumab in Advanced Squamous NSCLC. *Journal of Thoracic Oncology*.
- Bourliere M, …, **Huang KC**, …, Zeuzem S.
  Sofosbuvir, Velpatasvir, and Voxilaprevir for Previously Treated HCV Infection. *N Engl J Med.* doi: 10.1056/nejmoa1613512
- El-Sherif O, …, **Huang KC**, …, Curry M.P.
  Baseline factors associated with improvements in decompensated cirrhosis after direct-acting antiviral therapy for hepatitis C virus infection. *Gastroenterology*
- Edward G, …, **Huang KC**, …, Sulkowski M.
  Sofosbuvir-Velpatasvir with Ribavirin for 24 weeks in HCV Patients Previously Treated with a Direct-Acting Antiviral Regimen. *Hepatology.* doi: 10.1002/hep.29256
- Whyles D, …, **Huang KC**, …, Sulkowski M.
  Sofosbuvir and Velpatasvir for the Treatment of HCV in Patients Coinfected with HIV-1: an Open-Label, Phase 3 Study. *Clin Infect Dist*. doi: 10.1093/cid/cix260
- Zhang G, **Huang KC**, Xu Z, Tzeng JY, Conneely KN, Guan W, Kang J, Li Y.
  Across-Platform Imputation of DNA Methylation Levels Incorporating Nonlocal Information Using Penalized Functional Regression. *Genet Epidemiol.* 40(4): 333-40.
- **Huang KC**, Sun W, Wu Y, Mohlke KL, Lange LA, Li Y.
  Association Studies with Imputed Variants Using Expectation-Maximization Likelihood-Ratio Test. *PLoS ONE* 9(11): e110679.
- Kang J, **Huang KC**, Xu Z, Wang Y, Abecasis GR, Li Y.
  AbCD: Arbitrary Coverage Design for Sequencing-based Genetic Studies. *Bioinformatics* 29(6): 799-801. (Co-first Author)

EDUCATION

University of North Carolina, Chapel Hill, NC, USA May 2015
Ph.D. in Biostatistics

University of Michigan, Ann Arbor, MI, USA May 2010
M.A. in Statistics

COMPUTER SKILL

Formal language	C
Statistical Package	R, SAS, Matlab, WinBUGS, JMP, SPSS
Scripting Language	Perl, Python, C Shell
Other Software	Microsoft Word, Excel, and PowerPoint

HONOR & AWARD

Eli Lilly and company, Indianapolis, IL, USA
- Innovation Award 2025

Gilead Sciences, Inc, Foster City, CA, USA
- Values at Work Award 2016-2017

University of North Carolina, Chapel Hill, NC, USA
- Student Travel Award 2015

- Student Travel Award 2014

CONFERENCE

Talk

- **Gilead Sciences Biostatistics Seminar 2017**
  Dose Escalation Methods for Oncology Phase I Studies
- **Joint Statistical Meeting 2014**

Association Studies with Imputed SNPs Using Expectation-Maximization-Likelihood-Ratio Test

- **Eastern North American Region 2014**

Association Studies with Imputed SNPs Using Expectation-Maximization-Likelihood-Ratio Test

Poster

- **American Society of Human Genetics 2013**

Association Studies with Imputed SNPs Using Expectation-Maximization-Likelihood-Ratio Test

- **American Society of Human Genetics 2012**
  Patterns of Indel Variation: Comparison of Calling Methods and LD with SNPs