Akintunde (Tunde) Bello

Vice President of Clinical Pharmacology and Pharmacometrics, Bristol-Myers Squibb

Akintunde (Tunde) Bello is Vice President of Clinical Pharmacology and Pharmacometrics at Bristol-Myers Squibb and leads a cross-functional team of scientists working on early and late stage clinical development of novel immuno and targeted oncology therapies. Tunde also oversees the quantitative systems pharmacology, physiologically based pharmacokinetics and model based meta-analysis functions. Prior to his role at BMS, Tunde was a Clinical Pharmacology Group Leader at Pfizer Inc where he oversaw the life cycle management support of the oncology and pain and inflammation therapeutic areas. Tunde’s more than 25 years of pharmaceutical industry experience encompasses the areas of bioanalysis, preclinical DMPK and clinical drug development. He have supported the development, approval and life cycle management of more than 6 marketed drugs in the areas of oncology, pain management, inflammation and infectious disease. Tunde has a BSc in Medical Laboratory Sciences (Biomedical Sciences) from Portsmouth University (UK), an MSc in Instrumentation and Analytical Sciences from the University Of Manchester Institute Of Science and Technology (UMIST, UK) and a PhD in Pharmaceutical Sciences from King's College, University of London (UK). Tunde has authored/co-authored more than 70 peer reviewed abstracts and journal manuscripts and is a member of the American Society of Clinical Pharmacology and Therapeutics (ASCPT, served on the annual meeting organizing committee) and the American Society of Clinical Oncology (ASCO). He is the recent post Chair of the IQ Consortium Clinical Pharmacology Leadership Group.

Nageshwar Budha

Senior Director
Clinical Pharmacology, BeiGene

Nageshwar Budha has 12 years of industry experience in the areas of clinical pharmacology and pharmacoetics. He is currently working as Senior Director, Clinical Pharmacology at BeiGene and serves on the editorial board at the Clinical and Translational Science Journal. Before his current role, Dr. Budha worked in the clinical pharmacology group at Genentech with increasing roles of responsibility. Over the course of his career Dr. Budha worked on small molecule and large molecule drug development projects in oncology and non-oncology therapeutic areas and supported regulatory approvals. Dr. Budha received multiple recognition awards for his work and at the school. Dr. Budha received his PhD from the University of Tennessee Health Science Center at Memphis and his BS and MS degrees in Pharmaceutical Sciences from Kakatiya University, India.
Instructor Biographies

Justine Cunningham, PhD, DABT
VP, Toxicology & Biodistribution, Sana Biotechnology, Inc.

Justine graduated from The University of Queensland, Brisbane, Australia in 1998 with a PhD in Neuroscience. Thereafter she moved to Memphis to pursue her Post-doc at St Jude Children's Research Hospital on a cross functional project between the Dept's of Developmental Neurobiology and Tumor Cell Biology. Later she took a chance on a new gene therapy company in late 2001 pursuing genetic therapies to express neurotrophic factors for Parkinson's and Alzheimer's. Following that she has worked at a variety of small and mid-size pharma continuing in the space of advancing novel biologics, leading to the successful filing of multiple INDs and entry into patients. Today Justine leads Toxicology, Pathology, and Biodistribution at SANA Biotechnology. SANA is an emerging player in leveraging genetic technologies to deliver novel cell and gene therapeutic medicines to meaningfully improve patient outcomes and to make these broadly accessible to the people who need them.

Dolo Diaz, PhD
Head of Development Sciences, Denali Therapeutics

Dolo Diaz serves as the Head of Development Sciences at Denali Therapeutics. In this role she leads the DMPK, Clinical Pharmacology, Toxicology, Pathology and Nonclinical Operations teams in the advancement of Denali's portfolio of small molecules and biotherapeutics. Dolo was previously the Senior Director of Safety Assessment at Denali Therapeutics. In this role she built and led a group with expertise in toxicology, pathology and nonclinical operations. Prior to that Dolo was the Head of Discovery Toxicology at Genentech, where for nine years she led compound optimization and safety strategies for the small molecule discovery portfolio across therapeutic areas. Dolo started her industry career at Eurofins, where she established and headed the In-vitro Toxicology group. Dolo received her PhD in Toxicology from the University of Washington, followed by post-doctoral work at the Fred Hutchinson Cancer Research Center in Seattle. She has a BS in Pharmacy from the University of Santiago de Compostela (Spain). Dolo has authored more than 30 peer-reviewed publications and she is a Diplomate of the American Board of Toxicology.
Mika Derynck, MD

Chief Medical Officer, Amunix Pharmaceuticals

Mika Derynck has over 25 years of clinical academic, and drug development experience. She is currently the Chief Medical Officer at Amunix Pharmaceuticals working on pro-drug T-cell engagers and cytokines for oncology. Prior to Amunix, Mika was at Genentech/Roche for 15 years where she led the Franchises for Cancer Immunotherapy, Gastrointestinal/Genitourinary, and the China Development Team for Product Development Oncology. Before that she led the Breast Cancer Franchise. Prior to that she was in Early Development, gRED, where she had oversight on the PI3K, AKT, mTOR, MEK programs from preclinical to phase I and II. She has extensive regulatory experience from IND for first-in-human studies, phase II-III, global full and accelerated approvals, negotiation of post marketing requirements and conversions of accelerated approval, and registration of non-registrational studies (phase 2 or cooperative group study). Drugs include Avastin, Tecentriq, Perjeta, Cotellic, Taselisib, Pictilisib, Ipatasertib, Apitolisib, GDC-0810, GDC-0623, GDC-0349, anti-IGF1R. Mika is trained in Internal Medicine and Medical Oncology, having received her M.D. at Boston University, residency at Johns Hopkins University, and fellowship at University of California, San Francisco. Shortly after completion of her fellowship, she joined the faculty at UCSF and continued her clinical and translational research work in Prostate Cancer.

Mark Dresser, PhD

Senior Vice President, Biomarker Sciences & Clinical Pharmacology, Gilead Sciences
Adjunct Professor of Bioengineering and Therapeutic Sciences, UCSF

Mark Dresser has over 20 years of experience in medical product development spanning all phases of R&D in start-up, biotech, pharma, and academic environments. He currently serves as Senior Vice President, Biomarker Sciences and Clinical Pharmacology at Gilead Sciences, Adjunct Full Professor in the Department of Bioengineering and Therapeutic Sciences at UCSF, and as a Board Member of the American Society of Clinical Pharmacology & Therapeutics (ASCPT). Dr. Dresser’s prior appointments include, Senior Vice President, Development Sciences at Denali Therapeutics, Head of Oncology Clinical Pharmacology and Project Team Leader for the Anti-PD-L1 [Tecentriq®] program at Genentech. He began his career at ALZA Corporation, a Johnson & Johnson company. Over the course of his career, Dr. Dresser has played a key role in the advancement of over 45 investigational drugs into clinical testing and the global regulatory approval of four novel oncology therapies. In 2019, Dr. Dresser received the UCSF Graduate Division Alumnus of the Year Award for his contributions to science and medicine. Dr. Dresser received his PhD from the University of California at San Francisco and his BS and MS degrees in Chemistry from Rensselaer Polytechnic Institute and the Swiss Federal Institute of Technology.
Instructor Biographies

JW Feng, PhD

JW is a Staff Research Scientist and leads the drug discovery team in Google Accelerated Science. He is applying Google technologies, including deep learning, to accelerate the discovery of small molecule drugs. JW was an early employee in a biotech startup, Denali Therapeutics, where he built the molecular modeling and data science group to support both small molecule and biotherapeutics discovery. Key contributions from JW lead to the invention of multiple molecules entering clinical trials. Prior to Denali, JW was a Scientist at Genentech supporting small molecule drug discovery. JW received a PhD in Computational Biology at Washington University in St. Louis and bachelor of science degrees in Computer Science and Biochemistry at The Ohio State University.

Richard Graham, PhD

Richard A. Graham is Senior Vice President, Development, at Theravance Biopharma where he is responsible for leading the progression of late-stage clinical assets through regulatory filing and approval. Since joining Theravance Biopharma, Dr. Graham has served as Vice President of Clinical Pharmacology, and more recently, as Vice President of Clinical Development. Prior to joining Theravance Biopharma, Dr. Graham spent five years at GlaxoSmithKline working in the area of Drug Metabolism and Pharmacokinetics, seven years at Genentech/Roche as a clinical pharmacologist and Global Development Team Leader, and one year at Onyx Pharmaceuticals where he headed Translational Medicine. In his nearly 20-year career, he has worked across all stages of drug development and all major therapeutic areas. Dr. Graham received his Bachelor’s and Master’s degree in Biochemistry from Iowa State University and his Doctorate of Philosophy degree in Pharmaceutical Sciences from The University of North Carolina at Chapel Hill.
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<th>Instructor Biographies</th>
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<td>Conny Irl, PhD</td>
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<td>Senior Director</td>
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<td>Global Head of Oncology</td>
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<td>Biostatistics, Genentech</td>
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<td>Conny Irl has been working in the biotech/pharmaceutical industry for more than 20 years, across all phases of R&amp;D and multiple therapeutic areas. She is currently a Senior Director and Global Head for Oncology Biostatistics at Genentech, providing Biostatistics oversight for the late stage solid tumors portfolio. Dr. Irl started her career in the Biostatistics Department of Hoffmann-La Roche in Nutley, NJ, which she joined in 1999. In 2004, she transferred to the Roche Headquarters in Basel and in 2011 to Genentech in South San Francisco, which provided her unique opportunities to experience and bridge different cultures and work styles. During her time at Roche and Genentech, Dr. Irl has played a key role in the clinical development and regulatory approval of a number of oncology drugs, e.g. Alectinib™, Avastin™, Cotellic™ and Tecentriq. During her time at Roche and Genentech, Dr. Irl has also held a number of cross-functional leadership roles, such as Global Development Team Leader for Avastin Gynecological Cancers. Dr. Irl received her Ph.D. in Statistics from the Ludwig-Maximilians-University in Munich, Germany.</td>
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| David Kessler, MD       |
| Former FDA Commissioner |
| and Professor of Pediatrics and Epidemiology/ Biostatistics, UCSF |
| David A. Kessler, M.D., was the Commissioner of the Food and Drug Administration (FDA) from 1990 to 1997, under Presidents George H. W. Bush and Bill Clinton. He is a professor of pediatrics and epidemiology and biostatistics at the University of California, San Francisco (UCSF) and is the chair of the board of The Center for Science in the Public Interest (CSPI). He has served as the dean of the medical schools at Yale and UCSF. Dr. Kessler and his colleagues at the FDA acted to speed approval of new drugs and devices, while assuring their safety and efficacy, introduced the Nutrition Facts label, undertook the regulation of tobacco products, and created an Office of Criminal Investigation. Dr. Kessler is a graduate of Amherst College, the University of Chicago Law School, and Harvard Medical School. He was awarded the Public Welfare Medal from the National Academy of Sciences in 2001. Dr. Kessler, a member of the National Academy of Medicine, is the author of several bestsellers, including A Question of Intent, The End of Overeating, and Capture. His latest book is Fast Carbs, Slow Carbs. |
### Instructor Biographies

- **Patrick Loerch, PhD**
  
  Senior Vice President, Data Sciences & Biometrics, Gilead Sciences

  Patrick Loerch has over 20 years of experience in data sciences, real world evidence and genomics research spanning all phases of R&D within the pharmaceutical industry. Dr. Loerch currently serves as Senior Vice President, Data Sciences and Biometrics at Gilead Sciences. In addition to oversight of the existing Biometrics and Epidemiology organizations, Dr. Loerch is accountable for the build out and integration of Real World Evidence and Data Sciences capabilities to accelerate the discovery, development and delivery of new medicines. Dr. Loerch's prior roles include leadership positions at Johnson & Johnson, Celgene and Merck. He began his career at Rosetta Inpharmatics, a genomics start-up in Seattle, WA that was later acquired by Merck. Dr. Loerch received his PhD in Biostatistics from the Harvard University and his BS in Biochemistry from Washington State University.

- **Andrew McKee, MD**
  
  Founder, CEO, and President, Headland Strategy Group

  Andrew has over 15 years’ experience in biotechnology, pharmaceuticals, diagnostics, and other healthcare sectors. He founded Headland Strategy Group to build a team of smart, service-oriented problem-solvers who are passionate about health care innovation. He loves to build relationships, lead teams, teach, mentor, brainstorm, and work on difficult projects. Headland Strategy Group provides management consulting services for biopharma, diagnostics, digital health, and medical device firms. Headland’s value proposition is that they offer: 1) a hybrid strategy model (Commercial Strategy, BD/M&A/Partnering, and R&D/Portfolio Strategy); 2) deep expertise across diseases and technologies; 3) a flexible, results-oriented service that pairs well with fast-moving client teams; and 4) strong exposure to the US and Japan/S. Korea with offices and clients in the US and Japan. Headland is proud to serve distinctive clients such as Denali, NGM Bio, Alector, Gilead, Roche/Genentech, Theravance, Ultragenyx, Gyroscope, Olema, EA Pharma, SNBL, Alfresa Group, and many others. Andrew's background includes having worked for McKinsey and Company, Google, and Genentech. He holds B.S.E. and M.D. degrees from Duke University. He is a husband, father, mindfulness meditator, professional saxophonist, published writer, former scientist, and licensed patent holder.
Heleen Scheerens, PhD
Senior Director, Global Head OMNI-Biomarker Development, Genentech

Heleen has worked in the area of pharmacology for over 20 years and her interests are in understanding the mechanisms of action of novel therapeutics in human diseases, and using translational pharmacology to improve the effectiveness of clinical development. Currently, Heleen is the Global Head of Genentech’s OMNI-Biomarker Development department and leads a diverse group of >60 science professionals. Biomarker strategies from her group impact key drug development decisions in all phases of clinical development in Ophthalmology, Metabolism, Neuroscience, Immunology and Infectious diseases. Heleen has a passion for mentoring and is actively involved in gWise: Genentech Women in Science and Engineering, an organization committed to developing women leaders.

Prior to joining Genentech in 2006, Heleen held leadership positions at Celera Genomics and Rigel Pharmaceuticals. Heleen received her PhD in Immunopharmacology from the University of Utrecht, The Netherlands.

Kimberly Wilson, MS
Executive Director, Translational Epidemiology, Bristol Myers Squibb

Kimberly Wilson is an epidemiologist with over 20 years of health care research experience. Currently she is Executive Director, Translational Epidemiology at Bristol Myers Squibb. Her previous roles in industry have included pharmacovigilance and scientific stewardship in support of early and late stage drug development.

Prior to joining industry, she worked in academia and the Translational Research Trials Office at the Cincinnati Children’s Hospital where she managed investigator-initiated IND studies being conducted in children and adults with rare diseases. In this role, her work led to the first non-surgical therapy approved by the FDA for treatment of brain tumors occurring in Tuberous Sclerosis patients. Her work has led to multiple publications including publications in journals such as Chest and the New England Journal of Medicine.