

Jeff (Jeffrey R.) Sachs, PhD is a Distinguished Scientist in the Quantitative Pharmacology and Pharmacometrics Department ("QP2") in Merck* Research Laboratories, where he is responsible for modeling and simulation supporting vaccine program decisions from early discovery through late-stage clinical development. His publication areas include methods for and applications of pharmacometrics, biotechnology, and AI/ML. (*Merck & Co. Inc., Kenilworth, NJ, USA)

Dr. Sachs received his BS and MS in Applied Math from Brown University and his PhD in Math at MIT where he worked with Alan Grodzinsky on the electromechanochemistry of articular cartilage, supporting design of a minimally-invasive arthroscopic diagnostic

device. After postdoctoral appointments in Applied Physics (Tokyo Univ.), Biomedical Engineering (Northwestern Univ.), and Biotechnology (N.I.S.T.), he developed two successful biotechnology consulting businesses. He came to Merck in 1999 and worked on gene expression analysis, data mining, and SAR integration platforms. He was lead inventor of Merck's proteomics and metabolomics technology platforms. He led the therapeutic area-aligned modeling and simulation group, and lead the design, implementation, and global deployment of a web-based tool providing a user-friendly, non-technical, modeling interface for internal and external decision makers. That tool, used across many programs and therapeutic areas, helped Merck gain recommendations for compounds in over 40 countries. He led the department's efforts in infectious diseases, oncology, and strategy for digital health/adherence. He is currently the QP2 Therapeutic Area Lead for vaccines, and the QP2 Program Lead for the dengue vaccine program. He is active in editorial boards and committees for the Society for Industrial and Applied Mathematics (SIAM), and is a mentor for the Association for Women in Mathematics (AWM) and for ISoP.



Dr. Jos Lommerse is a Director Modeler Consultant at Certara's Integrated Drug Development division.

Jos has supported decision-making in pharmaceutical industry using a large variety of computational tools for almost 25 years.

His background is in chemical engineering. He obtained his PhD in bioorganic chemistry at the University of Utrecht, the Netherlands. After a five-year period at the Cambridge Crystallographic Data Centre, where he had carried out scientific analyses on crystallographic molecular databases, he joined the department of Molecular Design & Informatics at Organon in 2000. Jos contributed to multidisciplinary research

programs applying molecular modeling and structure-based drug design and introduced a company-wide intranet cheminformatics framework. Jos joined the Department of Clinical PKPD at MSD in 2011.

Jos currently works as a Director Modeling consultant for Certara. He leads and applies modeling & simulation efforts in all phases of clinical development as well as in translational PKPD in many different therapeutic areas, such as oncology, immunology, metabolic diseases, rare diseases,

vaccine and pediatric programs. He provides strategies and rationales in drug development programs and contributes to regulatory filings, both for small molecules and biologics. He applied his expertise in model-based meta-analyses (MBMA) for drug landscaping and selection. Jos also develops new computational tools to improve on efficiency in drug development programs.



Dr. Nele Mueller-Plock is a Director in Integrated Drug Development at Certara. Dr Mueller-Plock holds a degree in Pharmaceutical Sciences from the University of Muenster, Germany, and pursued her PhD in Clinical Pharmacy at the Martin-Luther-University Halle-Wittenberg, Germany, where she worked across disciplines on investigating Pharmacokinetics of Anti-infectives in seriously ill patients.

Nele held various positions in industry. She was a key contributor to establishing the Preclinical Modeling and Simulation group at Bayer Schering Pharma, helping to get company-wide acceptance of translational PK and PK/PD approaches for initial human dose

prediction. Later, she joined Nycomed in Germany.

In her new role, she supported drug development with modeling approaches for innovative clinical trial design and was a leader of Translational teams. In 2012, she joined Takeda Pharmaceuticals, where she led and designed pharmacometric activities for multiple global projects. Nele has experience across a wide range of therapeutic areas over all phases of drug development. With more than 15 years of experience, she is now a key driver of M&S and MBMA strategy development at Certara.



Anna Largajolli, PhD, is an Associate Director Modeler consultant at Certara's Integrated Drug Development division.

She holds a M.Sc. in bioengineering from Padova University and from the same university a PhD in Pharmacometric modelling with a focus in the diabetes area. She has around ten years of experience in modelling thanks to the different international experience in academia (Visiting PhD student in Cape Town University and Postdoctoral research fellow in Uppsala University) and industry (GsK). Her solid technical background combined with a strong interest in clinical pharmacology permit her to adapt efficiently to the different research challenges.

Anna has been working in Certara for more than 5 years as an Associate Director Modeler consultant. She has been involved in different phases of clinical development as well as translational PKPD where she applied Pharmacometric modelling for drug development and contributed to regulatory filings.



S. Y. Amy Cheung, PhD, is a Senior Director at Certara, leading a Quantitative Science Group (with scientists from the UK, Italy and Nordic regions) in Integrated Drug Development and she is the global lead of the the Certara Pediatric Integrated Practice Area. She also mentors the Certara-Monash University Fellowship and Pharmacometrics African programme. She is also a guest editor for IJAA, ADDR, and Frontiers in Pharmacology.

Dr Cheung obtained her PhD from the University of Manchester. After receiving her PhD, she worked at the Centre for Applied Pharmacokinetic Research (CAPKR) at The University of Manchester. Before joining Certara, she gained over a decade of experience at AstraZeneca (AZ), where she was a Senior Pharmacometrician. She was also a Project Manager and functional representative at the AZ

Pediatric Working Group, which consisted of 22+ cross-functional pediatric experts. During this time, she was also the company representative on IMI DDMoRe and co-led WPs, e.g. PMX-workflow and cardiovascular training.

She has been a member of the EFPIA MID3 workgroup since the 2011 EMA M&S workshop, which resulted in several white papers. She has expertise in pediatric/geriatric drug development, oncology, infection, CNS, vaccine, mAb, MIDD, structural identifiability, PBPK, and extrapolation. She is currently part of the IQ CPLG pediatric working group and co-chair of the PBPK pediatric subgroup.