

Welcome to the Phoenix User Group Meeting



AGENDA: NOVEMBER 17 - 18, 2020

NOVEMBER 17, 2020

** Scheduled in India Time Zone*

9:00 – 9:05 AM	Welcome to the 2020 Phoenix User Group Meeting Tomoo Shinya, General Manager, Asia Pacific, Certara
9:05 – 9:15 AM	Certara Overview Emi Akatsu, Director of Marketing, Asia Pacific, Certara
9:15 – 9:35 AM	The Phoenix Platform Evolution Chris Mehl, Associate Director, Pharmacokinetics Software, Certara
9:35 – 10:05 AM	Phoenix WinNonlin What Is New & Product Roadmap Chris Mehl, Associate Director, Pharmacokinetics Software, Certara
10:05 – 10:20 AM	Coffee Break 15 minutes
10:20 – 10:50 AM	Example of NCA Business Rules Used with Parameter Ratio Tool Chris Mehl, Associate Director, Pharmacokinetics Software, Certara
10:50 – 11:55 AM	Phoenix WinNonlin Bioequivalence Use Case Chris Mehl, Associate Director, Pharmacokinetics Software, Certara <ul style="list-style-type: none">• <i>Parallel</i>• <i>Crossover</i>• <i>Replicate design</i>• <i>FDA reference scale template</i>
11:55 – 12:35 PM	Phoenix IVIVC Toolkit Use Case Chris Mehl, Associate Director, Pharmacokinetics Software, Certara
12:35 – 12:40 PM	Wrap up Tomoo Shinya, General Manager, Asia Pacific, Certara

NOVEMBER 18, 2020** Scheduled in India Time Zone*

9:00 – 9:05 AM

Welcome to Day Two of the 2020 Phoenix User Group Meeting

Tomoo Shinya, General Manager, Asia Pacific, Certara

9:05 – 9:30 AM

[Keynote] Model-informed drug repurposing: COVID-19 and beyond

Kashyap Patel, PhD. Director of Pharmacometrics, Certara

9:30 – 10:05 AM

Next Generation Data and Model Repository – Integral

Kevin Trimm, Senior Director, Product Strategy & Services, Certara

10:05 – 10:20 PM

Coffee Break

15 minutes

10:20 – 10:55 PM

Overcoming CDISC Roadblocks with PK Submit

Kevin Trimm, Senior Director, Product Strategy & Services, Certara

10:55 – 12:05 PM

Phoenix NLME Use Case

Dr. Keith Nieforth, Senior Director, Pharmacometrics Software, Certara

- *FDA approval case study*
- *NLME vs. NONMEM*

12:35 – 12:40 PM

Wrap Up and Closing Remark

Tomoo Shinya, General Manager, Asia Pacific, Certara

OUR SPEAKERS**Tomoo Shinya****General Manager, Asia Pacific, Certara**

Tomoo is the general manager Asian Pacific at Certara since 2013. He has been working at software/ hardware companies for over 20 years where he has gained extensive experience in the pharmaceutical industry.

**Emi Akatsu****Director of Marketing, Asia Pacific, Certara**

Emi is Certara's Director of Marketing, Asia Pacific. Emi started her career at Walt Disney World Florida as a cultural representative and trainer. After she came back to Japan, she was involved in various marketing consulting projects at a marketing automation software company. In 2014, Emi has joined Sartorius as Head of Marketing Communication, Asia Pacific, to penetrate a market share in the analysis space especially in China.

**Chris Mehl****Associate Director, Pharmacokinetics Software, Certara**

Mr. Mehl is the Associate Director, Pharmacokinetics Software for Phoenix WinNonlin and IVIVC Toolkit. Prior to this role Chris was an instructor at Certara University. His educational background is a BS in Molecular Biology from the Ohio State University, and an MS in Pharmacology from the University of Wisconsin. He has conducted over 200 training courses with Certara products, such as Phoenix WinNonlin, IVIVC, NLME, and Trial Simulator. These include workshops at the US Food and Drug Administration, universities, customer sites, and courses open to the public.

**Dr. Keith Nieforth****Senior Director, Pharmacometrics Software, Certara**

Dr. Nieforth is the Associate Director, Pharmacometrics Software, which includes Phoenix NLME, Pirana, and Trial Simulator. Keith has more than 20 years of global drug development experience and held a variety of positions within Clinical Pharmacology at Roche, from direct project support roles supporting successful NDAs, to membership on the global Clinical Pharmacology Leadership Team as systems expert for the department.

In addition to his expertise in quantitative and systems aspects of drug development, Dr. Nieforth has a passion for understanding and optimizing the human aspects of successful systems implementation.

Keith has a Bachelor of Science in Pharmacy from The University of Connecticut, and PharmD from the Massachusetts College of Pharmacy.

**Kevin Trimm, MSc.****Senior Director, Product Strategy, Software, Certara**

Mr. Trimm is Certara's head of software product strategy and is responsible for establishing the vision, strategic objectives, and road maps for Certara's analytical and regulatory software. Prior to joining Certara in 2017, Kevin held a number of positions in contract research firms, including the global head of Pharmacokinetics and Statistics at Charles River Laboratories, where he gained extensive experience in software development, validation, and deployment in highly regulated environments. Kevin was also the co-founder of the consulting firm Montreal Pharmacokinetics Inc. that was later acquired by Certara. Kevin received his undergraduate degree from the University of Waterloo, and holds graduate degrees in Neurobiology and Experimental Medicine. Kevin has a passion for finding innovative technology solutions to complex business problems.

**Kashyap Patel, Ph.D.****Director of Pharmacometrics, Certara**

Kashyap Patel is Director of Pharmacometrics at Certara Strategic Consulting. His research interests include mechanistic PK/PD modelling of anticancer, antiviral and antimalarial drugs. Kashyap has over 10 years of postdoctoral experience in pharmacometrics and drug pharmacology. He has a broad range of expertise in pharmacokinetic and pharmacodynamic modelling, bioanalytical assay development and validation, cell culture and in vitro or in vivo evaluation. Past appointments include Modelling & Simulation (Monash University) and Cancer Pharmacology (University of Auckland).

**Cindy Liang****Associate Director, Enterprise Software, Certara**

Ms. Liang is the Associate Director, Enterprise Software, which includes Certara Integral and PK Submit. Prior to joining Certara, Cindy has over 10 years DMPK experience in the pharmaceutical and CRO industry, including preclinical and clinical environments. She started her career as a DMPK scientist at Merck Research Labs, then went on to hold key positions at international CROs. In addition to scientific experience and expertise, Cindy has additional significant professional experience with business operations, quality assurance, and business development. Cindy holds a Master's degree in Pharmacology and is a trained Pharmacist.

FAQ INSTRUCTORS FROM CERTARA UNIVERSITY



Chandramouli Radhakrishnan, Ph.D.

Support Analyst, Phoenix, Certara

Chandramouli Radhakrishnan is a support and training scientist at Certara. Chandramouli graduated with a doctoral degree from The University of Queensland, Australia, in Clinical Pharmacology. With his experience, he was able to increase awareness on Certara Softwares (Phoenix Winnonlin, NLME, IVIVC, PK Submit, Trial Simulator, and Integral) in teaching and academic research, as well as in Industry across South Asia Pacific and provide global support.



Takanori Ogawa, MS

Senior Application Scientist, Certara

Mr. Ogawa joined Certara in 2010 through the acquisition of Bellkey Science Inc., which was a distributor company of Phoenix products in Japan. During his time at the companies, he has provided scientific support for PK/PD modeling and simulation (M&S) analysis to scientists in the pharmaceutical industry, academia, and regulatory agencies of Asian countries such as Japan, Korea, and China. He also has conducted over 250 training courses in those countries. In the courses, he teaches scientific theory and practical applications in addition to software hands-on exercises so that attendees can readily practice the M&S approach to their own R&D project. He earned an MS in Environmental Science from the University of Tsukuba.

About Certara

At Certara, we accelerate medicines to patients, partnering with life science innovators. Together we advance modern drug development with biosimulation, regulatory science, and market access solutions.

For more information, visit www.certara.com.

