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# Certara and Monash University announces Industry Drug Development Fellowships

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**Fellows will receive academic training and industry experience in clinical pharmacology, pharmacometrics and regulatory science**


Certara®, the global leader in model-informed drug development, regulatory science, real-world evidence and market access services, and Monash University, on 25 June 2019, announced the recipients of the inaugural Certara-Monash University-Industry Drug Development Fellowships – Dr Katrina Hui, Dr Yu-Wei Lin, and Dr Zheng Liu.

This fellowship program was designed by Certara and Monash University to help prepare the next generation of industry-experienced drug development scientists through training in clinical pharmacology, pharmacometrics and regulatory science. Based at the Monash Institute of Pharmaceutical Sciences, the program provides a combination of academic coursework, hands-on industry training, international industry/academic placements, and research. The fellowship program is designed to address the industry growth and increased need for global talent in drug development and regulatory sciences. The fellows will contribute to the planning, execution and analysis of pre-clinical and clinical drug development and pivotal clinical trials leading to regulatory submission in Australia.

“Model-informed drug discovery and development (MID3) strategy underpins all stages of contemporary drug discovery and development programs. MID3 provides a quantitative framework to improve decision making and reduce risk and is used by global regulators to evaluate new drug submissions. As a result, there is a growing demand for staff with integrated drug development expertise, including skills in clinical pharmacology, pharmacometrics, and regulatory science mechanistic modelling,” said Leigh B. Farrell, PhD, FAICD, Senior Vice President, Commercial at Certara. “As the leader in MID3, Certara felt it was it imperative to partner with our long-time collaborators at Monash University and help to impart our knowledge and experience to postdoctoral students who are establishing their careers in this field.”

“We are delighted to welcome our first fellows to the Certara-Monash University-Industry Drug Development Fellowship Program. We have spent more than a year developing the curriculum for this new leadership program, ensuring that it contains the right mix of technical training, research, and real-world experience. We are now confident that our graduating fellows will not only excel at MID3 but be able to explain clearly the strategy they employed and the significance of their

findings to their peers, sponsors and regulatory agencies," said Director of the Monash Institute of Pharmaceutical Sciences, Professor Chris Porter.

**Introducing the New Fellows**

Dr Hui received her PhD in Pharmacy Practice from Monash University and is now using population pharmacokinetic (PK) methods to develop a model for inhaled oxytocin as a postdoctoral research fellow at the university. The goal for this project is to be able to use inhaled rather than injected oxytocin to protect pregnant women from potentially fatal haemorrhages during or after the birth of their babies in developing countries.

Dr Lin received his PhD in Pharmacy from the Advanced Drug Delivery Group at the University of Sydney, Australia. He specializes in pharmacokinetic/pharmacodynamic (PK/PD) modelling, quantitative systems pharmacology modelling, and antimicrobial systems pharmacology research, which enable him to help optimize antimicrobial dosage regimens.

Dr Liu received his PhD in Process Modeling in Chemical Engineering from Aalto University in Finland. He is now conducting population PK/PD modelling and clinical trial design as a pharmacometrician at the University of Newcastle and Royal Children's Hospital in the UK. In tandem, he is also serving as a pharmacometrician in the Department of Human Nutrition at the University of Otago in New Zealand, where he is performing parameter regression and data analysis under a Bayesian framework, and optimizing the clinical trial design.

The Certara-Monash University-Industry Drug Development Fellowship Program is supported by MTPConnect, the Medical Technologies and Pharmaceuticals Industry Growth Centre, through its Project Fund Program. Managing Director and CEO, Dr Dan Grant, said the Certara-Monash University program is an important initiative for growing Australia's MTP sector.

"We are excited to see the Certara-Monash University-Industry Drug Development Fellowship Program reach this key milestone. It is another step closer to achieving our collective vision of it becoming the premier drug development science training program in Australia and the broader Asia-Pacific region," Dr Grant said.

Underscoring the need for this advanced training program, Australia's Therapeutic Goods Administration, the China National Products Administration, European Medicines Agency, Japan's Pharmaceuticals and Medical Device Agency, the UK's Medicines and Healthcare Products Regulatory Agency, and US Food and Drug Administration are all increasing their use of modeling and simulation to evaluate new drug submissions. In fact, there are now more than 200 label claims on FDA-approved drugs that have been made using physiologically-based PK modelling alone, in lieu of a clinical study.