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Certara to bring Model-informed Precision Dosing into clinics

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Certara, the global leader in model-informed drug development, regulatory science, real-world evidence and market access services, announced its latest advances in bringing model-informed precision dosing (MIPD) to the point of care. Certara scientists have been engaged in critical assessments of hurdles to MIPD (starting with a white paper in 2017) and now have published four new MIPD papers in the past months delineating the vision and practical path(s) for making individualized dosing a reality under the efforts for “Precision Medicine.”

MIPD uses computer modeling and simulation to predict the drug dose for a given patient based on their individual characteristics, is most likely to improve efficacy and/or lower toxicity compared with traditional dosing. MIPD is particularly useful when dosing patients who belong to a vulnerable population, such as neonatal or pediatric patients, patients with significant renal or hepatic impairment or the frail elderly who receive multiple drugs and hence are susceptible to drug interactions.Those patients are at increased risk of drug-related harm, so improved dosing will likely enhance their care. This is a significant problem for society as well as individual patients because drug-related harm is estimated to cost about US $42 billion per annum globally.

“Certara recognized several years ago that model-informed drug development (MIDD) could also provide tremendous value if used by healthcare providers (HCPs) to determine the optimal drug dose for individual patients in the clinic,” said Certara Chief Scientific Officer Professor Amin Rostami.

“We decided to apply our experience in making MIDD operational by collaborating with colleagues in pharma, academia and global regulatory agencies in the area of MIPD to achieve widespread adoption and practical use in clinic instead of the current restricted applications in academic research settings,” Amin stated further.

This transition is being facilitated by several factors that are improving researchers’ understanding of inter- and intra-

individual variability in drug response. They include the availability of fast and affordable genetic testing, the rise of multi-omic technologies to identify biomarkers to monitor handling of the drug by individual patient and the specific effects in each patient, improved medical imaging, rapid pathology testing, characterization of the gut microbiome, superior analysis of biological samples, and powerful computational tools to analyze large quantities of patient data.

“MIPD will be especially valuable for HCPs dosing drugs with a narrow therapeutic index – where a small change in dose can have a large impact on the drug’s therapeutic effect or risk of an adverse reaction – and when treating patients from vulnerable populations, which tend to be more complex cases due to changing physiology or polypharmacy,” said Tom Polasek, MD, PhD, Medical Director of MIPD at Certara and lead author on three of the new MIPD papers. Drugs with a narrow therapeutic index include anti-arrhythmics, anti-coagulants, anti-epileptics, aminoglycoside antibiotics, and immunosuppressants.

Dr. Polasek is also a clinical pharmacology registrar at Royal Adelaide Hospital and an adjunct senior lecturer at the Centre for Medicines Use and Safety at Monash University in Australia.