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Certara forms new practice area to achieve health equity

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Aims to create novel and impactful drug development, regulatory science and patient access approaches that will deliver effective and affordable therapies to the global population

Certara®, the global leader in model-informed drug development, regulatory science, real-world evidence and market access services, has announced that it has formed a new practice area called Certara Global Health (CGH) to focus its technological expertise on helping to achieve equity in health for all people worldwide. CGH is a new product development innovation practice inspired by Certara's drug development and scientific due diligence work for the Bill & Melinda Gates Foundation.

"Certara Global Health will bring together talent, technology, software, systems and processes to accelerate the development of medicines for those that need them most," said Craig Rayner, PharmD, MBA, SVP and Co-Lead of CGH. "Working closely with the foundation and other leaders in the global health sector, CGH will focus on creating novel and impactful drug development, regulatory science and patient access approaches that will deliver effective and affordable therapies to populations in need around the world. A triple bottom line practice across the global health product development ecosystem."

"Developing medicines are expensive and difficult at the best of times, and securing talent and capital is an extra challenge for the global health sector," said Kevin Hershberger, BPharm, MBA, VP and Co-Lead of CGH. "But we are confident that we can play a catalytic role in bringing creative thinkers together with leading-edge technologies and methodologies, to support solving medicine development and access challenges in global health."

CGH will leverage Certara's cross-functional, interdisciplinary global scientific staff to create a 'sandbox of innovation.' CGH will employ:

- New quantitative drug development methodologies, such as model-informed translational medicine, innovative clinical trial designs, human infection models, quantitative systems pharmacology (QSP) and toxicology, and the full range of proven pharmacometrics capabilities (PK/PD, PBPK, etc.) to accelerate the drug development process;
- Novel regulatory science approaches to create precedents for increasing certainty in decision-making and expediting the regulatory review;
- New Chemistry, Manufacturing and Control (CMC) talent to tackle the toughest CMC challenges in delivering quality medicine to low-middle income countries;
- Innovation in accelerating access to medicine for global populations, leveraging new epidemiological models, real-world evidence, pharmacology-to-payer prototyping, early deployment approaches, and tools to support product distribution and access. CGH staff will also use new technologies and modalities to improve health literacy, clinical trial participation, medical adherence behaviour, infection surveillance and real-world data collection globally.
- Apply modelling and simulation in an integrated drug development environment to propel drug discovery and lead optimization. For example, using QSP alongside modern screening approaches to improve hit-to-lead, lead candidate selection, and first-in-human dosing strategy;
- Support due diligence of assets, stage-gate decisions and portfolio management to identify and triage optimal drugs for select populations;
- Develop technologies, software and processes across all areas to codify best practices, increase quality and support/enable best outcomes.

Certara continues to provide global health capabilities to the Gates Foundation as well as other not-for-profit organizations, traditional pharmaceutical companies, and governments. Recent examples include Certara’s collaboration with Medicines Development for Global Health (MDGH) on its FDA new drug approval for moxidectin as an oral treatment for river blindness, a neglected tropical disease; its partnership with the Australian Department of Defence to audit the nation’s medical countermeasures preparedness and advance novel products towards the clinic; and its selection by the US Centers for Disease Control & Prevention to develop a technology platform to strengthen the agency’s death investigation and surveillance systems.