

Curriculum Vitae

Personal information Hsiao-Tzu Chien

Work experience

July 2021 - present, PhD candidate/Non-clinical assessor, Radboud University Medical Center/Medicines Evaluation Board, the Netherlands

Carry out non-clinical assessment.

Conduct research to identify regulatory opportunities and challenges to improve non-clinical requirements in drug development.

Specific research topics include: 1) Re-evaluating the need for chronic toxicity studies with therapeutic monoclonal antibodies, using a weight-of-evidence approach; 2) Developing a roadmap towards a human-centric assessment of ATMPs; 3) Establishing criteria to waive the need for an enhanced pre- and post-natal developmental toxicity study for therapeutic monoclonal antibodies; 4) Gap analysis of regulatory space in veterinary and human non-clinical study package requirement.

July 2020 - July 2021, Researcher, Medicines Evaluation Board, the Netherlands

Lead analyst of an EPAA-funded research project where the need for chronic toxicity studies with therapeutic monoclonal antibodies was evaluated.

July 2019 - Feb 2022, Research Intern, Medicines Evaluation Board, the Netherlands

Feb 2018 - Mar 2019, Research Intern, UMC Utrecht, the Netherlands

Nov 2016 - May 2017, Researcher, Veterinary Medicines, Utrecht University, the Netherlands

May 2016 - May 2017, Anesthesiologist Intern, Veterinary Medicines, Utrecht University, the Netherlands

Sep 2012 - Feb 2016, Veterinarian, Zoo-Ann Animal Hospital, Ner Taipei City, Taiwan

April 2011 - April 2012, Clinical Intern, Rakuno Gakuen University, Hokkaido, Japan

Education and training

Feb 2018 - Feb 2020, Master of Science (MSc), Utrecht University, the Netherlands

Sep 2007 - Jun 2013, Doctor of Veterinary Medicine, Collage of Veterinary Medicines, National Chung Hsing University, Taichung City, Taiwan

Sep 2003 - Jun 2007, Bachelor in Biological Science, National Sun Yat-Sen University, Kaohsiung City, Taiwan

Additional information

Publications

Chien et al., 2023. Re-evaluating the need for chronic toxicity studies with therapeutic monoclonal antibodies, using a weight-of-evidence approach. Regulatory Toxicology and Pharmacology. 138 (2023)105329.

Projects

Memberships

Other Relevant Information