## Yale SCHOOL OF PUBLIC HEALTH Biostatistics

"HCOMBS: Hierarchical Bayesian Clustering Design of Multiple Biomarker Subgroups"

Jun (Vivien) Yin, PhD, Assistant Professor of Biostatistics at Mayo Clinic

12:00 noon Eastern Time, February 11, 2021 Virtual Seminar via Zoom

Join from PC, Mac, Linux, iOS or Android: <u>https://yale.zoom.us/j/97988213411</u> Or Telephone : 203-432-9666 (2-ZOOM if on-campus) or 646 568 7788 Meeting ID: 979 8821 3411

**Abstract:** The paradigm for cancer clinical trials has shifted towards individualized treatment due to the blooming discoveries of biomarkers and targeted agents. Because of the deficiencies of screening agents or testing histologic tumor types one at a time, basket and umbrella trials are emerging. We proposed Hierarchical Bayesian Clustering Design of Multiple Biomarker Subgroups (HCOMBS) for designing and conducting umbrella trials, to evaluate biomarker-treatment pairing and identify patient subpopulations that are most likely to benefit from novel agents. Compared to parallel design for individual cohorts, the HCOMBS designs have greatly reduced sample size, and hence improve efficiency and decreases the financial costs. We further extended it to allow the parallel cohorts to be dynamic, so that at interim analysis investigators can 1) eliminate or graduate molecular subgroups, and 2) cluster subgroups that exhibit similar response to treatment to improve power. The designs were calibrated with respect to specific error rates. We conduct extensive simulations to assess the performance and illustrate with a genomically-guided treatment trial in brain metastases (A071701) conducted by the NCI cooperative group Alliance for Clinical Trials in Oncology.

**Brief Bio:** Dr. Yin is an Assistant Professor of Biostatistics at Mayo Clinic, as well as adjunct Assistant Professor of Biostatistics at the University of Iowa. Dr. Yin has been heavily involved in multi-center cancer clinical trial research: she served as the Mayo UM1 consortium statistician for the NCI Experimental Therapeutics Clinical Trial Network (ETCTN) from 2015-2020, and a faculty statistician for the Alliance for Clinical trials in oncology (NCI cooperative group) since 2016. In addition to clinical trial research, she co-directs the Biostatistics and Bioinformatics Core for the Mayo Clinic Hepatobiliary Specialized Programs of Research Excellence (SPORE), nation's first SPORE focused on hepatobiliary cancer.

During her time at Mayo Clinic, Dr. Yin has developed a productive research portfolio in clinical trial methodology for dose-finding trials and master protocol studies, surrogate endpoint evaluation, and prognostic/predictive biomarker studies. She has published 34 peer-reviewed manuscripts with 9 as first or senior author.

