Mathematics, Statistics, and Computer Science **@ UIC**

Statistics and Data Science Seminar

A statistical roadmap for journey from real-world data to real-world evidence

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Abstract: Abstract: Randomized controlled clinical trials (RCTs) are the gold standard for evaluating the safety and efficacy of pharmaceutical drugs, but in many cases their costs, duration, limited generalizability, and ethical or technical feasibility have caused some to look for real-world studies as alternatives. On the other hand, real-world data may be much less convincing due to the lack of randomization and the presence of confounding bias. In this article, we propose a statistical roadmap to translate real-world data (RWD) to robust real-world evidence (RWE). The Food and Drug Administration (FDA) is working on guidelines, with a target to release a draft by 2021, to harmonize RWD applications and monitor the safety and effectiveness of pharmaceutical drugs using RWE. The proposed roadmap aligns with the newly released framework for FDA's RWE Program in December 2018 and we hope this statistical roadmap is useful for statisticians who are eager to embark on their journeys in the real-world research.

Wednesday, October 16 at 4:00 PM in 636 SEO