

Department of Epidemiology Johns Hopkins Bloomberg School of Public Health 415 N. Washington Street, 2<sup>nd</sup> Floor Baltimore, Maryland 21231

21 March 2022

## Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Real world evidence

Some days back I got a note from Tianjing Li with a journal article taking aim at the term "real-world evidence" with the question whether I had written on the topic. I have not – but will now.

The article to which Tianjing referred was published in the Journal of Clinical Epidemiology (142: 2022: 249–251) entitled Let's end "real-world evidence" terminology usage, authored by Rafael Leite Pacheco, Ana Luiza Cabrera Martimbianco, and Rachel Riera. The authors write "Real-world evidence" is a term that has been extensively presented in the medical literature in contemporary times. Its meaning is elusive, but this term is usually used to refer to evidence collected outside controlled experimental studies, such as randomized controlled trials (RCTs). A broader definition of "real-world evidence" is "data collected during the routine delivery of health care". Variations of this term include "real-world data" or "real-world study."

In the language of Mona Lisa Vito in My Cousin Vinny "it's a bullshit term". Devoid of meaning and pejorative to boot.

Usage implies that "real world data" are a cut above all others. A term of arrogance.

Evidence in Merriam-Webster is an outward sign or something that furnishes proof. "Real world evidence" is neither. The term has no place in scientific literature or discourse. It is vacuous and pejorative, implying that the data that matter are "real world".

The inexorable standards in medical research are data collected via IRB approved protocols and formal data analyses to assess differences. There is no yellow road to success with "real world data", however collected.

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