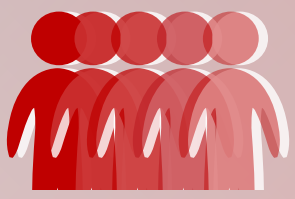
A NEW MODEL FOR LARGE-SCALE REAL WORLD DATA ANALYSIS

THE OPPORTUNITY

Understanding how medicines are experienced in a real-world setting provides important information for improving patient outcomes. Real World Data (RWD) can often complement evidence generated from clinical trials by showing how treatments work in the real world across a large number of patients. However, analyzing very large, fragmented data sets continues to be a challenge for researchers, inhibiting the ability to fully capture tangible insights from RWD.

Research by Johnson & Johnson's epidemiology team suggests a new model to faciliate RWD analysis.

A CASE HISTORY: OBSERVE-4D STUDY*



Researchers analyzed data from **714,582 adults with Type 2 Diabetes** across **4 U.S. databases**

Including employer-sponsored health insurance plans, Medicaid and Medicare

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Using open-source analytical tools, made available through OHDSI

192 analyses were performed

Across **7 different medications** or classes of medications, **2 health outcomes,** and the **4 databases**

Resulting in **10,752 effect estimates**

A WEB-BASED TOOL WAS CREATED to make the study protocol, source code and results publicly available

WHAT IS THE VALUE OF THIS NEW MODEL?

The model, as illustrated through the OBSERVE-4D study, provides a new, transparent methodology for quickly and appropriately translating large-scale RWD into evidence, in near real time, to complement evidence from clinical trials and inform patient care and treatment decisions. While important, real-world studies have limitations and cannot be used as stand-alone evidence to validate the efficacy or safety of a treatment.

Enables
BROAD APPLICATION OF FINDINGS

Supports
GENERALIZABILITY & ROBUSTNESS OF FINDINGS

Facilitates
USE & REPLICATION FOR FUTURE RESEARCH

* Learn more about the OBSERVE-4D study here. Full study results have been published in *Diabetes, Obesity & Metabolism*.

Johnson & Johnson