Real Real World Evidence

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http://www.ohdsi.org

“The sole cause and root of almost every defect in the sciences is this: that whilst we falsely admire and extol the powers of the human mind, we do not search for its real helps.”

— Novum Organum: Aphorisms [Book One], 1620, Sir Francis Bacon
When comparisons were made between NOACs, matched rivaroxaban patients had a significantly higher risk of major bleeding (HR: 1.82; 95 % CI: 1.36–2.43) compared to apixaban patients.
Studies ignore...

- Selection bias
- Measurement error
- Model misspecification
- Multiple modeling
- Unmeasured confounding

Artisanal, non-reproducible, non-evaluable process
Observational research results in literature

85% of exposure-outcome pairs have $p < 0.05$

29,982 estimates
11,758 papers
A New Approach

• Reproducible, systematized, open source approach at scale

• Negative controls
  – Drugs and outcomes “known” to have no causal association
  – Literature, product labels, spontaneous reports
  – Empirical p-values

• Positive Controls
  – Inject signals onto negative controls with known effect size
  – Calibrated confidence intervals
Welcome to OHDSI!

The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. All our solutions are open-source.

OHDSI has established an international network of researchers and observational health databases with a central coordinating center housed at Columbia University.

Read more about us, about our goals, and how you can help support the OHDSI community.

Join the Journey

ACHILLES Released

OHDSI released its first open-source software application, ACHILLES, at the 2014 ESM Forum in San Diego, CA. Congratulations to the ACHILLES community.

OHDSI on YouTube

Welcome to OHDSI

Latest News

- OHDSI paper published in Drug Safety

search here … Go
Electronic Health Records ~ 700M
Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis

Marc A Suchard, Martijn J Schuemie, Harlan M Krumholz, Seng Chan You, RuiJun Chen, Nicole Pratt, Christian G Reich, Jon Duke, David Madigan, George Hripcsak, Patrick B Ryan

All pairwise comparisons of 39 drugs, 58 outcomes, 9 databases
LEGEND Large-scale Evidence Generation and Evaluation in a Network of Databases

40 trials \rightarrow 10,278 comparisons

https://github.com/OHDSI/LEGEND
Concluding thoughts

• An international community and global data network can be used to generate real-world evidence in a secure, reliable and efficient manner

• Common data model critically important

• Much work remains on establishing (and improving) actual operating characteristics of current approaches to causal inference