



Scientifically validated software for performing rapid-cycle analytics™ to generate real-world evidence at scale.

Our data scientists and a network of academic and industry partners continually test the Aetion Evidence Platform® to ensure transparency and accuracy.

Validation against published studies

Using the Aetion Evidence Platform, a Harvard Medical School team led by Shirley V. Wang reproduced 31 published studies with a wide range of designs in two commercial databases and one EHR database. [1] The project, [REPEAT](#), is the largest real-world data reproducibility study ever completed. Funded by the John and Laura Arnold Foundation, Dr. Wang is now embarking on an even larger validation study to define the field of health care database analytics. Using the Aetion Platform, her team will reproduce 250 published studies across commercial and Medicare claims and EHR databases.

Validation against FDA Sentinel

The FDA Sentinel system is the established standard for decision-makers using health care database analytics. In extensive testing, the Aetion Evidence Platform has demonstrated a high degree of accuracy against a range of FDA modular programs.

Validation against randomized trials

A collaborative team from the Brigham and Women's Hospital and a sponsor conducted a multi-database cardiovascular safety study as a post-marketing commitment and completed the study within six months. At the time of publication, a parallel randomized control trial was in process. When the RCT was completed, it confirmed the exact results obtained using real-world evidence and the Aetion Evidence Platform. [2] Today, Aetion is embarking on a systematic reproduction of completed and ongoing RCTs using real world data in collaboration with health care data scientists from Harvard.

Validation through teaching

Aetion works closely with academic partners to teach database analytics. Annually, about 100 students take courses on database analytics for effectiveness research using the Aetion platform at Harvard and in Europe. Students in the course come from ministries of health, health plans, the biopharma industry and academia to implement their own projects using a variety of designs to evaluate the effectiveness of health care interventions and medical products.



Validation through leadership in transparency and reproducibility

Aetion co-founder Sebastian Schneeweiss is co-lead of the joint ISPE/ISPOR Task Force on transparency in database research in health care. The task force is producing consensus papers on best practices to ensure transparency for the process of designing and implementing database studies.

Validation of the MVET framework of RWE for confident decision making

A joint work group of NEWDIGS (MIT), European Medicines Agency, and IMI ADAPT SMART has developed a framework that helps evaluate whether real-world evidence can support decision making in life sciences and clinical care. The consensus document is supported by regulators (EMA, FDA), Health Technology Assessment agencies, payers, biopharma companies and academics. [3]

The four components of the so-called MVET framework – meaningful evidence, valid evidence, expedited evidence, and transparent evidence – are the pillars of the Aetion Platform.

Validation through independent double programming

Every dataset connected to the Aetion Platform is subjected to a rigorous quality control process that includes double programming, where analytical results of the Platform are validated against results obtained by data scientists using independent software.

References

[1] Wang SV, Verpillat P, Rassen JA, Patrick A, Garry EM, Bartels DB. *Transparency and reproducibility of observational cohort studies using large healthcare databases*. Clin Pharm Ther 2016;99:325-32

[2] Kim SC, Solomon DH, Rogers JR, Gale S, Klearman M, Sarsour K, Schneeweiss S. *Cardiovascular safety of tocilizumab versus tumor necrosis factor inhibitors in patients with rheumatoid arthritis – a multi-database cohort study*. Arthritis Rheumatol 2017; 69:1154-1164.

[3] Schneeweiss S, Eichler H-G, Garcia-Altes A, Chinn C, Eggimann A-V, Garer S, Goettsch W, Lim R, Loebker W, Martin D, Mueller T, Park BJ, Platt R, Priddy S, Ruhl M, Spooner A, Vannieuwenhuyse, Willke RJ. *Real world data in adaptive biomedical innovation: A framework for generating evidence fit for decision making*. Clin Pharm Ther 2016;100:633-46