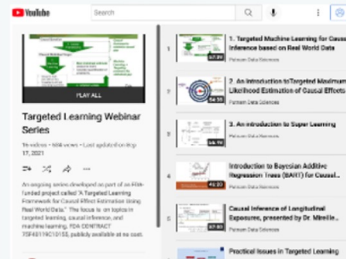


Comparative Effectiveness: Targeted Learning FDA Demonstration Project

Resulted in various
collaborative relations with
FDA statisticians

TL for RWE multi-year FDA-funded project

TL on YouTube



Publications with FDA co-authors

Targeted learning: Towards a future informed by real-world evidence

Susan Gruber, Rachael V. Phillips, Hana Lee, Martin Ho, John Concato,
Mark J. van der Laan

The 21st Century Cures Act of 2016 includes a provision for the U.S. Food
and Drug Administration (FDA) to evaluate the potential use of real-world
evidence (RWE) to support new indications for us

Evaluating and improving real-world evidence with Targeted Learning

Susan Gruber, Rachael V. Phillips, Hana Lee, John Concato, Mark van der
Laan

Purpose: The Targeted Learning roadmap provides a systematic guide for
generating and evaluating real-world evidence (RWE). From a regulatory
perspective, RWE arises from diverse sources such as randomized controlled trials
that make use of real-world data, observational studies, and other study designs.
This paper illustrates a principled approach to assessing the validity and
interpretability of RWE.



Over 250 FDA short course attendees

SHORT COURSE ANNOUNCEMENT



A Targeted Learning Framework for Causal Effect Estimation
using Real-World Data

Funded by FDABAA-19-00123-A3