CURRICULUM VITAE

Date Prepared:	April 1, 2021
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Place of Birth:	Philadelphia, PA

Education

1990 **BA in Economics/Political Science**
Tufts University

1992 **MA in Economics**
Tufts University

2002 **PhD in Social Policy**
Brandeis University
Advisor: Stanley Wallack, PhD

2016 Wharton Executive Education, The Leadership Edge
The Wharton School, University of Pennsylvania

Faculty Academic Appointments

2005-2009 **Lecturer**
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2009-2014 **Assistant Professor**
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2014- **Associate Professor**
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

Other Professional Positions

1999-2000 **Consultant**
Formulary Analysis Committee
Institute of Medicine's Veterans Affairs

2000-2005 **Senior Research Associate**
Boston Health Economics, Inc.

2008-2010 **Consultant**

Phase Forward Inc., Lincoln Safety Group

2009-2012 **Member, Health Informatics Advisory Board**
Observational Medical Outcomes Partnership
Foundation for the National Institutes of Health

2010-2016 **External Expert Advisory Committee**
ASthma SafEty obServational Study (ASSESS)
GlaxoSmithKline (GSK)

2010- **Affiliated Faculty**
Center for Biomedical Innovation, New Drug Development Paradigms Initiative (NEWDIGS)
Massachusetts Institute of Technology, Boston, MA

2012-2013 **Consultant**
Oracle

2012-2013 **Expert Consultant**
A Study on the Impact of Various Bias Parameters on Study Designs Using Quantitative Bias Analysis via Simulations and to Develop a User-friendly Statistical Tool for Future FDA Use
Scimetrika, Food and Drug Administration (HHSF223201210329A)

2013 **Expert Consultant**
Cohort Builder for Healthcare Quality
Commonwealth Informatics, US Dept of Defense (W81XWH-13-C-0029)

2014-2016 **Consultant**
NCI Community Oncology Research Program (NCORP)
University of Rochester Medical Center

2015- **Member**
Planning Board and Science Committee, Biologics and Biosimilars Collective Intelligence Consortium
Academy of Managed Care Pharmacy/ BBCIC

2015 **Visiting Expert**
Health Manpower Development Plan
Ministry of Health, Singapore

2015- **Member, Inaugural Editorial Board**
2021- **Assistant Editor**
Learning Health System Journal

2017-2018 **Member, Scientific Advisory Board**

Reproducible Evidence: Practices to Enhance and Achieve Transparency (REPEAT) project.
Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital

2017-2020 **Consultant**
IBM

2018-2019 **Commissioner, CDISC Blue Ribbon Commission**
Clinical Data Interchange Standards Consortium (CDISC)

2018-2019 **Consultant**
Roche

2018-2019 **Consultant**
Bayer Oncology

2018- **Member, NESTcc Data Quality Subcommittee**
National Evaluation System for health Technology Coordinating Center (NESTcc), Medical Device Innovation Consortium (MDIC)

2019- **Member, Scientific Advisory Committee**, Solriamfetol Pregnancy Studies
Jazz Pharmaceuticals, Inc

2019- **Consultant**
Mathematica Policy Research

2019- **Co-chair, Scientific Advisory Board**
TriNetX

2019- **Consultant**
COR Analytics, now Forian

2020 **Member, COVID-19 Vaccine Advisory**
Janssen Infectious Diseases and Vaccines

Major Administrative Leadership Positions

Local

2005-2018 **Research Director**
Division of Therapeutics Research and Infectious Disease Epidemiology (TIDE)
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2007-2010 **Site Data Manager**
HMO Research Network Cancer Research Network
Department of Population Medicine

Harvard Medical School and Harvard Pilgrim Health Care Institute

2009-2016 **Director, Data Group and Executive Committee Member**
FDA Mini-Sentinel Project Coordinating Center
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2010- **Leadership Committee\ Strategy Board Member**
Division of Therapeutics Research and Infectious Disease Epidemiology (TIDE)
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2016-2019 **Executive Committee Member**
FDA Sentinel Coordinating Center
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2019- **Executive Committee Member, Lead Data Scientist for Network Operations**
FDA Sentinel Coordinating Center
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

National

2005-2010 **Director**
HMO Research Network CERT Data Coordinating Center
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

Committee Service

Local

2006-2008 **Member**
Data Strategies Committee
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2007 **Member**
Faculty Search Committee, Health Informatics
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2007-2008 **Member**
CTSA Grant Subcommittee 3 – Bioinformatics
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2007-2008 **Member**
Electronic Data Warehouse Data Integration Team
Harvard Pilgrim Health Care Institute

2008 **Member**
Faculty Search Committee, Health Policy/Economics
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

2008-2010 **Member**
Biomedical Informatics Core
Harvard Clinical and Translational Science Center
Harvard Medical School

2008-2010 **Member**
Community Engagement and Research Core
Harvard Clinical and Translational Science Center
Harvard Medical School

2013-2014 **Chair**
Faculty Search Committee, Pharmacoepidemiology
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

National

2006-2009 **Member**
Cancer Research Network's Scientific Data and Resources Core
HMO Research Network

2006-2007 **Member**
Health Information Technology Committee
HMO Research Network Coordinate Clinical Studies Network

2007-2010 **Chair**
Virtual Data Warehouse Operational Committee
HMO Research Network

2007-2010 **Member**
Assets Stewardship Committee
HMO Research Network

2008-2010 **Chair**
Virtual Data Warehouse Pharmacy Working Group
HMO Research Network

2008-2010 **Member**

EPIC Strategic Recommendations Workgroup
HMO Research Network

2008-2010 **Member**
Administrative Workgroup
HMO Research Network

2011-2012 **Member**
Technical Architecture and Core Data Model Subcommittee
Multi-Payer Claims Database Governing Board, HHS/ASPE

2011-2012 **Member**
Query Health Initiative Clinical, Operational, and Technical Workgroup
Standards & Interoperability Framework, Office of the National Coordinator for Health Information Technology

2011-2012 **Member**
Scientific Program Committee
AMIA Annual Symposium, 2012
American Medical Informatics Association (AMIA)

2011-2012 **Member**
VDW Review Committee
Health Informatics Review Committee
HMO Research Network

2012 **Member**
Kanter Learning Health System Summit
Joseph H. Kanter Family Foundation

2012-2013 **Member**
Planning Committee
Identifying the Research Challenges Underlying a National-Scale Learning Health System
National Science Foundation

2012-2013 **Member**
Planning Committee
Data Quality Assessment for CER
EDM Forum, AcademyHealth

2013-2014 **Member**
Inaugural Steering Committee
The Learning Health Community

2013 **Member**

AMCP Task Force on Biosimilar Collective Intelligence Systems
Academy of Managed Care Pharmacy (AMCP)

2014 **Co-Chair**
Planning Committee
Distributed Analysis in Data Networks
PCORnet Network Research Methods Work Group

2016 **Member**
Planning Committee
Second Learning Health System Summit

2019 - **Member, Board of Directors**
Learning Health Community, Inc.

2020 - **Member, RWE Collaborative COVID-19 Working Group**
Duke-Robert J. Margolis, MD, Center for Health Policy

Professional Societies

2002-2009 **International Society for Pharmacoeconomics & Outcomes Research**
- 2006-2010 Abstract Selection Committee

2004-2010 **American Public Health Association**

2005-2009 **Society for Medical Decision Making**

2006-2010 **Drug Information Association**

2007- **International Society of Pharmacoepidemiology**
- 2008-present Database Methods Working Group
- 2009-present Abstract Selection Committee

2009- **American Medical Informatics Committee**
- 2012 Scientific Program Committee
- 2013, 2015, 2017 Abstract Selection Committee

2011-2017 **AcademyHealth**

Grant Review Activities

2008 **Ad hoc Grant Reviewer**
Cancer Research Network

2011 **Grant Reviewer**
Drug Safety and Effectiveness Network (DSEN): Drug Safety and Effectiveness Network Collaborating Centre for Prospective Studies
The Canadian Institutes of Health Research (CIHR)

2011 **Grant Reviewer**
Drug Safety and Effectiveness Network (DSEN): Network Meta-Analysis and Innovative RCT Designs
The Canadian Institutes of Health Research (CIHR)

2012 **Grant Reviewer**
Harvard Catalyst SHRINE Query Prize Program and the Harvard Catalyst SHRINE Pilot Funding Program
Harvard Medical School

2012 **Grant Reviewer**
Rapid Funding for Drug Safety and Effectiveness Network (DSEN) Targeted Research
The Canadian Institutes of Health Research (CIHR)

2017 **Grant Reviewer**
2016 Project Grant competition
The Canadian Institutes of Health Research (CIHR)

2018 **Grant Reviewer**
2017 Project Grant competition
The Canadian Institutes of Health Research (CIHR)

2019 **Grant Reviewer**
Drug Safety and Effectiveness Network (DSEN) team grants: MAGIC and CAN-AIM
The Canadian Institutes of Health Research (CIHR)

2019 **Grant Reviewer**
Methodology Research Panel
Medical Research Council, UK Research and Innovation

Editorial Activities

Ad hoc Reviewer

- Journal of General Internal Medicine
- Medical Care
- Managed Care Interface
- Value in Health
- Neurology
- Health Affairs
- Pharmacoepidemiology and Drug Safety
- Statistics in Medicine
- Journal of Biomedical Informatics
- eGEMs
- Expert Opinion in Drug Safety
- CNS
- Lancet
- Epidemiology
- Pediatrics
- Therapeutics Advances in Drug Safety
- Vaccine
- JAMIA
- Journal of Comparative Effectiveness Research
- Nature Communications

- Learning Health System Journal
- JCO Clinical Cancer Informatics
- The Journal of Delivery Science and Innovation
- Journal of the American College of Surgeons

Honors and Prizes

2006, 2008 **Exceptional Reviewer**
Medical Care

2008 **Best Paper (Lead Author), Pharmacoepidemiology and Drug Safety, 2007**
International Society of Pharmacoepidemiology

2012 **Best Paper (Co-Author), Honorable Mention, Pharmacoepidemiology and Drug Safety, 2012**
International Society of Pharmacoepidemiology

2009, 2011, 2013 **Exceptional Reviewer**
Pharmacoepidemiology and Drug Safety

2013 **Best Papers in Clinical Research Informatics (Co-Author), 2013**
2013 International Medical Informatics Association (IMIA) Yearbook

2018 **Best Paper (Co-Author), Honorable Mention, Pharmacoepidemiology and Drug Safety, 2017**
International Society of Pharmacoepidemiology

2020 **FLC Technology Transfer Award: FDA MyStudies App**
Federal Laboratory Consortium

Report of Funded and Unfunded Projects

Past funded projects
Grants while a doctoral student at Brandeis University

1999-2000 **Dissertation**
Agency for Health Care Policy and Research
Role: PI ($20,000)
Research grant to support my dissertation research.

Research conducted as a research associate at the Tufts Center for the Study of Drug Development

1993-1995 **Availability of anticancer drugs in the United States, Europe, and Japan: 1960-1991**
Tufts University, Center for the Study of Drug Development
Role: Junior Investigator
Assess the availability of anti-cancer medications in the US, Europe, and Japan, and to identify variation in access and potential causes and impacts.

1994-1995 **The Food and Drug Administration's early access and fast-track approval initiatives: how have they worked?**
Tufts University, Center for the Study of Drug Development
Role: Junior Investigator
Review the Food and Drug Administration's efforts to speed access to important new therapies through new regulatory initiatives that reduced the burden for marketing approval.

1995-1996 **Regulatory review times of supplemental indications for already-approved drugs: 1989 to 1993.**
Tufts University, Center for the Study of Drug Development
Role: Junior Investigator
Compare the Food and Drug Administration's review time for supplemental indications for already-marketed products.

Research conducted as a senior research associate at <u>Boston Health Economics, Inc</u>.

2000-2002 **Effect of the Heart at Work program on awareness of risk factors, self-efficacy, and health behaviors.**
Pfizer Outcomes Research
Role: Lead Investigator
Assess the impact of the American Heart Associations' Heart At Work program.

2001-2002 **Trends in the use of lipid-lowering medication and attainment of cholesterol goal.**
Pfizer Outcomes Research
Role: Lead Investigator
Using linked administrative and electronic medical record data, assessed use of lipid-lowering medications and the rate of cholesterol goal attainment.

2002-2006 **Migraine prevention and the cost-effectiveness of topiramate.**
Ortho-McNeil Pharmaceutical
Role: Lead Investigator
Series of studies that included (1) a report on the effectiveness, use, and cost of migraine prevention therapies; (2) development of an international budgetary impact model for topiramate in migraine prevention; (3) development of a cost-effectiveness model for topiramate, and (4) assessment of the overall and health-specific quality of life of migraine patients.

2003-2004 **Episodes of respiratory care for managed care patients with COPD: Assessing the economic burden.**
Pfizer Outcomes Research
Role: Lead Investigator
Identify and describe episodes of COPD using administrative data by development of algorithms that linked unique encounters into an episode of care.

2003-2008 **MRI of fetal ventriculomegaly: morphology and outcome.**
NIH (5R01EB001998; PI: D Levine)
Role: Consultant
Design a project-wide double-entry data collection system that allowed data capture of information on pregnancies, births, and up to 5 years of follow-up. Also developed and implemented data validation activities and participated in manuscript development.

2004 **Using health-risk appraisal data in health services research: Issues, examples, and opportunities.**
Boston Health Economics Inc. and BCBS Rhode Island
Role: Lead Investigator
Assess the potential of using routinely-collected health risk assessment data to augment observation studies through improved ascertainment of potential confounders.

2004-2006 **Pharmacy cost comparison: Neighborhood Health Plan, 340B program, and MassHealth.**
Medmetrics, Inc.
Role: Lead Investigator
Series of analyses comparing costs of pharmacy dispensings across various distribution channels and development of a budgetary model to help assess policy options for MassHealth.

2004-2006 **Respiratory Health Promotion Study**
Pfizer Outcomes Research
Role: Lead Investigator
Prospective, longitudinal study initiated as part of employer and community wellness activities offered by a local health plan. Goals were to assess the burden of respiratory disease, identify the rate of undiagnosed disease, and assess the quality of life of patients with COPD.

Research conducted while at the Department of Population Medicine

Funding amounts for privately funded activities is redacted.

2004-2007 **The HMO Coordinated Clinical Studies Network (CCSN)**
NIH (HHSN268200425216C; PI: R Platt)
Role: Investigator
Build on the current capacity of the HMO Research Network to create a research facility for clinical and health services research. Specific goals include improving internal and external communication; reducing scientific, administrative and economic barriers to multi-site collaboration in clinical studies; building common IRB, patient retention and recruitment and clinical studies procedures.

2004-2009 **A population based approach to signal detection: Data mining the HMO Research Network.**
Pfizer (PI: R Platt)

Role: Investigator
Assess data mining approaches for adverse event signal detection using population-based observational data. Includes adaptation of the commonly-used Gamma Poisson Shrinkage approach for surveillance data.

2005-2009 **HMORN CERT Developing Evidence to Inform Decisions about Effectiveness: The DEcIDE Network**
AHRQ (HHSA290200500331; PI: R Platt)
Role: Investigator
The DEcIDE Network will facilitate studies of the comparable effectiveness, safety, and cost-effectiveness of therapies and health services within populations often excluded from randomized clinical trials.

2005-2010 **Epidemiologic Studies of Adverse Effects of Marketed Drugs**
FDA (HHSF223200051000012C; PI: R Platt)
Role: Investigator
Use the automated and medical records of managed care organization populations to rapidly evaluate safety and utilization pattern of marketed prescription drugs.

2006-2007 **The HMO Research Network Centers for Education and Research on Therapeutics (CERT II)**
AHRQ (5U18HS010391-07; PI: R Platt)
Role: Investigator
Conduct timely research on the use, safety, and effectiveness of therapeutics using health plans' defined populations, providers, delivery systems, and data.

2006-2007 **Using Electronic Health Data to Assess Influenza Vaccine Safety.**
FDA (200-2002-00732; PI: R Platt)
Role: Co-PI ($246,000)
Goals are to (1) improve the nation's ability to use electronic health data for rapid assessment of adverse reactions to influenza vaccine, including pandemic influenza vaccine; and (2) expand the size of the population for which electronic health data can be used for influenza vaccine, including pandemic influenza vaccine, safety assessment.

2006-2010 **ADHD Drugs and Cardiovascular Outcomes –Full Study**
AHRQ (HHSF223200510012C, COA 6; PI: R Platt)
Role: Investigator
Retrospective, multi-institutional cohort study of the use of medications for ADHD and the risk of serious cardiovascular outcomes such as sudden cardiac death, stroke, and arrhythmias. Study includes use of observation data as well as review of full-text medical records.

2006-2010 **Risk of Guillain-Barré Syndrome Following Meningococcal Conjugate (MCV4) Vaccination**
Sanofi-Aventis (NCT00575653; PI: R Platt)

Role: Investigator
Large multi-site retrospective study of the relationship between immunization with MCV4 and Guillain-Barré Syndrome in adolescents. The relationship between GBS and other vaccine types also will be assessed.

2007-2008 **Pneumonia and Upper Respiratory Tract Infections Among COPD Patients using Fluticasone/Salmeterol in Combination Versus Other Steroids and Bronchodialators Alone.**
GlaxoSmithKline via Lovelace Clinic Foundation (PI: D Mapel)
Role: Investigator
Examine whether COPD patients prescribed Advair have a higher risk for pneumonia as compared to patients who are treated with other ICS and/or bronchodilators alone.

2007-2008 **Using Electronic Health Data for Influenza Vaccine Safety: New Methodologies and Considerations.**
FDA (HHSF223200710017C; PI: R Platt)
Role: Co-PI ($114,000)
Expand the previous influenza vaccine activities related to implementation and interpretation of sequential methods for active flu safety surveillance, assessment of key methodological considerations in conducting real-time surveillance using administrative claims data, and assessment of issues related outcomes occurring on the same day as vaccination.

2007-2009 **Task Order 5, Developing a Distributed Research Network and Cooperative to Conduct Population-based Studies and Safety Surveillance.**
AHRQ (HHSA29020050033I; PI: R Platt)
Role: Investigator
Design a scalable, secure, distributed health information network—a distributed research network—to conduct population-based studies of the risks and benefits of therapeutics.

2007-2009 **Electronic Support for Public Health: Vaccine Adverse Event Reporting System (ESP: VAERS)**
AHRQ (1R18HS017045; PI: R Platt)
Role: Investigator
Goal is to improve the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). Electronic medical records from ambulatory care encounters in a multi-specialty practice will be used to test the potential for improving VAERS reporting.

2007-2012 **Cancer Research Network Across Health Care Systems (CRN 3)**
NIH (1 U19 CA128294-01; PI: E Larson)
Role: Investigator

Conduct research that improves the effectiveness of cancer prevention and treatment through research that identifies individual, provider, system and treatment factors that affect outcomes.

2007-2012 **HMO Research Network CERT III Core**
AHRQ (1U18HS016955-1; PI: R Platt)
Role: Investigator
Conduct timely research on the use, safety, and effectiveness of therapeutics using health plans' defined populations, providers, delivery systems, and data.

2008-2009 **Defining and Evaluating Database Models**
FDA (HHSF223200831315P; PI: R Platt)
Role: Co-PI ($64,000)
Assess user needs for a proposed FDA Sentinel Network and define several potential database models that can meet those needs; compare and contrast the different database models.

2008-2009 **Prospective Surveillance for Adverse Drug Reactions**
AHRQ (1U18HS016955; PI: R Platt)
Role: Co-PI ($218,000)
Implement a proof-of-principle prospective evaluation of the safety of a newly marketed drug product to test the feasibility of using sequential analytic methods for active drug safety surveillance.

2009-2010 **Harvard Clinical and Translational Science Center (Harvard Catalyst)**
NIH (1 UL1 RR 025758-01; PI: R Platt)
Role: Investigator
Provide enriched resources to educate and develop the next generation of researchers trained in the complexities of translating research discoveries into clinical trials and ultimately into practice. Design new and improved clinical research informatics tools for analyzing research data and managing clinical trials.

2009-2010 **Post-Licensure Rapid Immunization Safety Monitoring System (PRISM) for H1N1 Vaccine**
CDC (200-2002-00732; PI: R Platt)
Role: Investigator
Create a distributed health plan data network to support urgent CDC need to enable capacity for surveillance of the safety of the H1N1 influenza vaccine.

2009-2011 **Developing a Distributed Research Network and Cooperative to Conduct Population-based Studies and Safety Surveillance (DRN2)**
AHRQ (HHSA29020050033; PI: R Platt)
Role: Investigator
Conduct studies on therapeutic safety and effectiveness using multiple sources of electronic health information. The primary goals are to improve public knowledge about health outcomes faster than traditional research approaches, and to take

advantage of research networks to detect important sentinel events, identify rare adverse effects of treatment, and assess long-term outcomes of treatments.

2009-2011 **Data Mining Electronic Health Records for Drug Adverse Events**
NIH (1RC1LM010371-01) (with M. Kulldorff)
Role: PI ($978,927)
The project addresses the challenge of using informatics for post-marketing surveillance. Two data mining methods, empirical Bayes gamma Poisson shrinkage and the tree-based scan statistic, will be used to search for unexpected acute drug adverse events using electronic health records database from three health insurance plans. Signals will be evaluated logistic regression analyses and temporal scan statistics.

2009-2019 **Efforts to Develop the Sentinel Initiative**
FDA (HHSF223200910006I; PI: R Platt)
Role: 2009–2016 Director of Scientific Systems
2014–2019 Member of the Sentinel Operations Center Executive Committee
Create a "laboratory" for developing and evaluating scientific methodologies that might later be used in a fully-operational Sentinel Initiative, and to offer FDA the opportunity to evaluate safety issues in existing automated healthcare data system(s) and to learn more about some of the barriers and challenges.

2010-2011 **Medication Safety Studies in Population-Based Health Networks - Improving Control of Confounding: Expansion of a Study of the Generic Introduction of Divalproex Sodium**
FDA (HHSF223200510012C; PI: R Platt)
Role: Co-PI
Expand prior work evaluating the safety of a newly-introduced generic drug to better understand potential sources of bias and confounding to inform medical product surveillance activities. Specific aims include assessing the incorporation of "control" medications and outcomes to identify potential bias and confounding; and evaluation use of regression analysis rather than stratification to better control for confounding within a distributed data environment.

2010-2013 **The Developing Evidence to Inform Decisions about Effectiveness-2 (DEcIDE-2) Network**
AHRQ (HHSA290201000008I; PI: R Platt)
Role: Investigator
The DEcIDE-2 network supports AHRQ's response to the Medicare Modernization Act's mandates for comparative effectiveness and safety research. The Network develops scientific evidence and methodologies about the outcomes, comparative effectiveness, safety, and appropriateness of health care items and services for improving the quality, effectiveness, and efficiency of healthcare.

2010-2015 **Cervical Dysplasia in Patients with Rheumatoid Arthritis**

NIH (1K23AR059677-01; PI: S Schneeweiss)
Role: Site PI
The study goal is to examine the incidence rate of high-grade cervical dysplasia and cervical cancer in rheumatoid arthritis patients compared to controls in a large commercial insurance claims database. Project includes development and testing of an algorithm to identify high-grade cervical dysplasia and cervical cancer patients in administrative claims databases.

2010-2013 **Scalable PArtnering Network for CER: Across Lifespan, Conditions, and Settings (SPAN)**
AHRQ (1R01HS019912-01; PI: J Steiner)
Role: Site PI
Develop an interoperable distributed research network and governance approach that will support comparative effectiveness research using patient-reported data collected at the point of care and real-time data collection.

2011-2012 **Identifying Treatment Resistant Depression in Automated Databases**
AHRQ (1R03HS019024-01A1; PI: R Platt)
Role: Investigator
Develop and validate algorithms to identify treatment-resistant depression in administrative claims databases to support subsequent studies of the long-term comparative effectiveness and safety of various therapeutic options for treatment-resistant depression.

2011-2013 **MDPHnet**
ONC (EP-HIT-10-002; PI: M Klompas)
Role: Investigator
We will create MDPHnet, a scalable, transportable, open source, distributed-data, distributed-analysis system that allows public health agencies to use Electronic Health Records data without requiring transfer of Protected Health Information. This automated distributed analytic tool will use normalized data across multiple health systems to enable standardized reports and customized queries.

2012-2017 **Cancer Research Network Across Health Care Systems (CRN 4)**
NIH (1U24CA171524-01; PI: L Kushi)
Role: Investigator; Informatics Core co-lead
Conduct research that improves the effectiveness of cancer prevention and treatment through research that identifies individual, provider, system and treatment factors that affect outcomes.

2012-2017 **Health Care Systems Research Collaboratory - Coordinating Center**
2017-2022 NIH (1U54AT007748-01; PI: L Curtis)
Role: 2012-2017 EHR Core co-lead;
2017-2022 Member of DRN Group
Collaboratory Coordinating Center works with NIH Pragmatic Trials Demonstration projects to partner with health care systems, produce, document,

and disseminate standards and create durable infrastructure to facilitate multi-site studies and reuse of data. The grant is led by Duke University.

2013-2014 **Evaluating the Massachusetts Department of Public Health Prevention and Wellness Trust Fund**
MA DPH (PI: M Klompas)
Role: Investigator
The objectives are to assess the capabilities of the Massachusetts All Payer Claims Database and MPDHnet to 1) evaluate the impact of the Massachusetts Department of Public Health Prevention and Wellness Trust Fund grants on healthcare utilization, patterns of care, and outcomes, and 2) explore how various data sources could be used to expand public health surveillance activities.

2013-2015 **PCORI National Patient-Centered Clinical Research Network Coordinating Center**
PCORI, (PCO-COORDCTR2013; PI: R. Platt and A. Hernandez)
Role: Investigator; Data Standards, Security, Networking, and Infrastructure Task Force co-lead
The Coordinating Center provides support for the National Clinical Research Network (NCRN). Specific aims are to (1) create a research-ready NCRN (PCORnet) comprising PCORI-funded Clinical Data Research Networks and Patient-Powered Research Networks, and (2) ensure PCORnet leverages the resources of existing multipurpose clinically embedded networks.

2013-2016 **Building PCORI Value and Integrity with Data Quality and Transparency Standards**
PCORI (ME-1303-5581; PI: M Kahn)
Role: Investigator
The objectives of the study are (1) to develop community-driven consensus recommendations for data quality (DQ) reporting; (2) to develop terminology describing the data collection context (e.g, data observer, measurement method, validation processes), collection intent (e.g. clinical care versus research), and collection meta-data; (3) to develop prototype DQ reports and visualizations that are intuitive and informative to data users and results consumers; and (4) to promote the adoption and reporting of standard data collection meta-data, and DQ assessment. The grant is led by University of Colorado, Denver.

2015 **AMCP Planning Grant: Biologics and Biosimilars Collective Intelligence Consortium**
AMCP
Role: PI, Analytic Coordinating Center
The Academy of Managed Care Pharmacy is planning to create the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) to assess the safety and effectiveness of biosimilars and biologics. BBCIC plans to leverage FDA Sentinel data and infrastructure. The six-month planning phase will focus on the consortium's governance and research framework.

2015-2016 **Innovation in Medical Evidence Development and Surveillance (IMEDS) Evaluation Pilot Project**
Pfizer via the Reagan-Udall Foundation for the FDA
Role: PI, Analytic Coordinating Center
The Innovation in Medical Evidence Development and Surveillance (IMEDS) program is part of the Reagan-Udall Foundation for the FDA (RUF) established by Congress through the FDA Amendments Act of 2007 (FDAAA) to advance the regulatory science needs of the FDA. This pilot project assesses how medical product sponsors can use data and tools developed by FDA Sentinel. The evaluation focused two use cases: oral contraception and risk of VTE and the impact of a labeling change on PPI use.

2015-2017 **Cross-Network Directory Service (CNDS)**
FDA (HHSF223201400030I / HHSF22301006T)
Role: PI ($1,500,000)
The objective of this project is to develop and implement a secure distributed data infrastructure that provides interoperability across existing networks. This infrastructure will enable investigators to discover sources, share data, and send and receive queries while ensuring their governance rules are enforced.

2015-2018 **PCORI National Patient-Centered Clinical Research Network Coordinating Center**
PCORI, (PCO-CC2-Duke-2016; PI: R Platt and A Hernandez)
Role: Investigator; Distributed Research Network Operations Center co-lead
The PCORnet Coordinating Center's primary goal is to enable distributed research across the network of PCORnet network partners and to support specific PCORnet studies. Specific responsibilities include operation and management of the secure distributed querying infrastructure and oversight of the development and use of PCORnet distributed querying infrastructure and tools.

2015-2018 **Collection of Participant-Provided Information through a Mobile Device Application**
FDA (HHSF223201400030I / HHSF22301006T)
Role: PI ($2,000,000)
Develop a generalizable mobile app to capture data from pregnant women (i.e., medical product exposures, outcomes, risk factors, and confounders) that will be linked with a single data partner from Sentinel or PCORnet.

2016-2017 **UCB Collaborative Research Network**
UCB (AH000622)
Role: PI
The primary objectives are to create and implement a collaborative research network to support UCB medical product safety and effectiveness research needs. First project is an assessment of the rate of treatment for newly diagnosed epilepsy patients.

2016-2018 **PCORnet Bariatric Study**
PCORI (OBS-1505-30683; PI: D Arterburn)
Role: Co-Investigator
Estimate the 1-, 3-, and 5-year benefits and risks of the three most common bariatric procedures within PCORnet Clinical Data Research Networks. My role focuses on the effective use of the PCORnet data model and electronic data to support the study aims.

2016-2018 **Short- and Long-term Effects of Antibiotics on Childhood Growth**
PCORI (OBS-1505-30699; PI: J Block)
Role: Co-Investigator
Assess the effects of antibiotic use in the first two years of life on growth trajectories, BMI, and obesity in mid-childhood. My role focuses on the effective use of the PCORnet data model and electronic data to support the study aims.

2016-2019 **Use of the ADAPTABLE Trial to Strengthen Methods to Collect, Validate, and Integrate Patient-reported Information with Electronic Health Record Data**
Supplement to the NIH Health Care Systems Research Collaboratory
(HHSF 3U54AT007748-05S1; PI: A Hernandez)
Role: Site PI ($250,000)
The ADAPTABLE trial aims to identify the optimal dose of aspirin therapy for secondary prevention in atherosclerotic cardiovascular disease. The goal of this project is to develop, pilot and evaluate methods to validate and integrate patient-reported information with data obtained from the EHR, and generate tools and data standards that could be deployed more broadly.

2016-2019 **Standardization and Querying of Data Quality Metrics and Characteristics for Electronic Health Data**
FDA (HHSF223201400030I / HHSF22301006T)
Role: PI ($1,750,000)
The primary objectives of the project are to create and implement a metadata standards data capture and querying system for data quality and characteristics (including completeness, comprehensiveness, accuracy, consistency, and validity); data source and institutional characteristics; and fitness-for-use.

2017-2018 **Innovation in Medical Evidence Development and Surveillance (IMEDS)**
Eli Lilly via the Reagan-Udall Foundation for the FDA (AH000641)
Role: PI, Analytic Coordinating Center and Site PI
IMEDS is a public-private partnership within Reagan Udall Foundation for the FDA that has a core goal to support the FDA's Sentinel system. This project assessed the rate of VTE among patients with rheumatoid arthritis. Results were presented by the sponsor FDA in support of a new drug application.

2018-2019 **Opioid Rapid Cycle Research**

Louisiana Public Health Institute (CDRN-1306-04864/ AH000669; PI: T Carton)
Role: Site PI
Project goals are to develop a "PCORnet Opioid Surveillance Demonstration" effort that will complement existing and support future opioid epidemic surveillance efforts led by multiple public stakeholders.

2018-2019 **Harmony Sub Study**
GlaxoSmithKline via Duke Clinical Research Institute (AH000655; PI: L Curtis)
Role: Site PI
This project is related to a sub-study of the GSK Harmony clinical trial. The sub study focuses on the use of EHR data to support study outcome assessment. We will provide PopMedNet configuration, network and hosting support, and project leadership to support the 12 participating Data Partners.

2020 **Feasibility Assessment: Post-marketing safety surveillance to monitor joint safety events in all patients using tanezumab and those with long-term use**
Pfizer via Reagan-Udall Foundation for the FDA (IMEDS-Merck-AH000750A)
Role: PI, Analytic Coordinating Center and Site PI
The study will describe the population of patients with osteoarthritis, pain treatment history, incidence of total joint replacement, and the availability of medical charts, including electronic health record data, to identify rapidly progressive osteoarthritis type 2, osteonecrosis and subchondral insufficiency fracture among those with total joint replacement.

Past unfunded projects

2011-2012 **Standard approaches and practical considerations in evaluating data validity for comparative effectiveness research in distributed data networks**
AcademyHealth EDM Forum
Role: PI
The primary aims are to 1) describe a framework for implementing data quality checking for comparative effectiveness research (CER) in distributed data networks, and 2) provide specific examples of data quality checking approaches across various CER scenarios.

Current funded projects

2016-2021 **Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)**
AMCP (AH000585)
Role: PI
The goal is to establish a distributed research network focused on generating evidence on the clinical outcomes of novel biologics, biosimilars, and related products. The scope includes population characterization and evidence generation on clinical effectiveness and safety outcomes.

2016-2021 **A Pregnancy and birth outcome assessment in a population-based cohort after exposure to Trumenba®: Coordinating Center Activities**
Pfizer (AH000604, AH000643)
Role: PI
The purpose of this project is to assess pregnancy and birth outcomes in women and infants, respectively, in a population-based cohort after exposure to the vaccine Trumenba® prior to or during pregnancy. This focuses on feasibility querying and preparation for Phase 2 project activities.

2017-2021 **Database cohort study to assess the risk of serious angioedema in association with LCZ696 (sacubitil/valsartan; Entresto®) use in Black patients with heart failure in the United States**
Novartis via the Reagan-Udall Foundation for the FDA (IMEDS-Novartis-AH000653, AH000673)
Role: PI, Analytic Coordinating Center and Site PI
This non-interventional cohort study aims to characterize the incidence and relative risk of serious angioedema in Black and non-Black patients with heart failure exposed to sacubitril/valsartan compared to ACE inhibitors.

2018-2022 **Post-Authorization Safety Study to assess the risk of Diabetic Ketoacidosis among Type 2 Diabetes Mellitus patients treated with Ertugliflozin compared to patients treated with other Antihyperglycemic Agents**
Merck via Reagan-Udall Foundation for the FDA (IMEDS-Merck-AH000671)
Role: PI, Analytic Coordinating Center and Site PI
The goal of this project is to develop a research protocol for submission to the European Medicines Agency to conduct an epidemiological study to compare the risk of diabetic ketoacidosis (DKA) with use of ertugliflozin compared to the risk of DKA in other antihyperglycemic agents and to conduct feasibility assessments to support study implementation.

2018-2021 **Evaluation of Real World Nucala® Use in the United States Using a Distributed Data Network**
GlaxoSmithKline (GSK-1118-AH000686)
Role: PI
The goal of this project is to characterize mepolizumab (Nucala®) treatment patterns and users and investigate the real-world effectiveness and comparative effectiveness of mepolizumab.

2018-2021 **Comparative Effectiveness of Biologic or Small Molecule Therapies after Failure of Anti-TNF Treatment in Patients with Crohn's Disease and Ulcerative Colitis**
University of North Carolina -Chapel Hill (AH000696; PI: M Kappelman)
Role: Site PI
To evaluate the effectiveness of biologic or small molecule therapies after failure of anti-TNF treatment in patients with Crohn’s disease and ulcerative colitis.

2018-2022 **Effects of Medical Products on Suicidal Ideation and Behavior-Real World Evidence**
Kaiser Foundation Research Institute (HHSF223201810201C; PI: G Simon)
Role: Investigator
A comprehensive program of infrastructure development, methods development, and innovative research to generate real-world evidence to address critical gaps in suicide ideation research.

2018-2022 **FDA MyStudies App: Alignment with Pragmatic Trials and Registries**
FDA (HHSF22301011T; PI: R Platt)
Role: Workgroup Lead
The purpose of this project is to enhancement the FDA MyStudies mobile application platform and enable implementation of the app to facilitate collection of patient-reported data from pragmatic trials and registries.

2019-2024 **FDA Sentinel Initiative**
FDA (75F40119F19001; PI: R Platt)
2019- Member of the Sentinel Operations Center Executive Committee
2019- Lead Data Scientist for Network Operations
Maintain and expand the Operations Center for the Sentinel System, a national active surveillance system to monitor the safety of marketed medical products.

2019-2026 **Targeted Safety Study for Shingrix in the United States (EPI-ZOSTER-030)**
GlaxoSmithKline (AH000692)
Role: PI
The project will develop a study protocol and statistical analysis plan for submission to the FDA as part of a post marketing safety requirement for Shingrix. We will also conduct a feasibility assessment based on the study protocol and review the literature to better understand how to identify outcomes of interest using observational data.

2019-2021 **FDA MyStudies App System Support**
FDA (HHSF22301011T; PI: R Platt)
Role: Workgroup Lead
The purpose of this project is to coordinate and provide support for open source comments and needed enhancements for the FDA MyStudies mobile application platform as directed by FDA.

2020-2022 **GSK Pregnancy Exposure Study: Nucala and Benlysta**
GlaxoSmithKline (114256)
Role: PI
The goal of this study is to use health plan claims data and claims data linked to electronic health record (EHR) data to identify and characterize the use of Nucala (mepolizumab) and Benlysta (belimumab) during pregnancy and among females aged 10-54 years of age. The study will also describe women with systemic lupus erythematosus who are unexposed to Benlysta during pregnancy. Claims data

linked to EHR data will be used to assess clinical information, including selected laboratory results.

2020-2021 **Phase 1b: Pregnancy Exposures and Outcomes in Women with Psoriasis Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States**
Abbvie via Reagan-Udall Foundation for the FDA
Role: PI, Analytic Coordinating Center and Site PI
The objectives of this project are to support development of study protocol for FDA submission, responses to regulator comments, protocol revisions and finalization of the statistical analysis plan.

2020-2021 **Active Surveillance Study of Post-Vaccination Events of Interest among Patients Vaccinated with Pfizer-BioNTech COVID-19 Vaccine**
Pfizer
Role: PI
The goal of this project is to develop a protocol for a non-interventional, post-authorization safety study for submission to FDA to evaluate the safety of Pfizer/BioNTech COVID-19 vaccine in populations post FDA Biologics License Application (BLA) approval.

2020-2022 **Pfizer Lyme Disease Algorithm Validation Study**
Pfizer (AH000796)
Role: PI
The primary objective of this study is to identify an algorithm to estimate Lyme disease cases in medical administrative claims data and validate the algorithm using medical charts. This study also will: 1) Describe the incidence of Lyme disease and associated manifestations by age; and 2) Compare the incidence of disease in the administrative claims database with the MA surveillance data to determine a local multiplier, by local, region, and/or state, depending on publicly-available data and the distribution of cases within the HPHC data.

2021-2023 **An Observational Post-Authorization Safety Study to Assess the Safety of Ad26.COV2.S Using Health Insurance Databases in the United States**
Janssen (AH000807)
Role: PI
The goal of this project is to develop a protocol for a non-interventional, post-authorization safety study for submission to FDA to evaluate the safety of Ad26.COV2.S COVID-19 vaccine in selected populations and to monitor the use of the vaccine after launch.

Report of Local Teaching and Training

Teaching of students in courses

2007, 2008, 2013 **AC511.0: Clinical Epidemiology and Population Health**
Tutor

Two 2-hour sessions per week for 4 weeks
1st year medical students; Harvard Medical School

2013 **CBMI 702.1: Introduction to Biomedical Informatics II**
Lecturer
One 3-hour session
Center for Biomedical Informatics students; Harvard Medical School

2013 **Introduction to Clinical Investigation, HMS Catalyst**
Speaker
One 1-hour session
Fellows and junior faculty; Harvard Medical School

2014 **CMBI 726: Big Data Innovations in Population Health**
Speaker
One 1.5-hour session
Informatics, business, public health, and Kennedy students; Harvard Medical School

2016 **EPI235: Epidemiologic Methods in Health Services Research**
Speaker
One 2-hour session
Harvard T.H. Chan School of Public Health, MD, MPH, ScD students

2017 **EPI235: Use of Electronic Healthcare Databases in Health Services Research**
Speaker
One 2-hour session
Harvard T.H. Chan School of Public Health, MD, MPH, ScD students

2018 **EPI235: Use of Electronic Healthcare Databases in Health Services Research**
Speaker
One 2-hour session
Harvard T.H. Chan School of Public Health, MD, MPH, ScD students

2018 **Essentials 2.0- Detecting population health problems with data**
Speaker
One 2-hour session
Harvard Medical School, 3rd and 4th year medical students

2019 **Essentials 2.0- Detecting population health problems with data**
Speaker
One 2-hour session
Harvard Medical School, 3rd and 4th year medical students

2020 **AISC 624.0 - Medications and Evidence: Understanding the effectiveness, risks, outcomes, costs, and regulation of prescription drugs**

Speaker
One 2-hour session
Harvard Medical School, 4th year medical students

2020 **Yale Law School**
Speaker
One 30-minute session
Yale School of Public Health MPH and Yale Law School students

2020 **Boston University School of Public Health**
Speaker
One 2-hour session
Boston University School of Public Health epidemiology students

Formally supervised trainees and faculty

Pre-doctoral

2009-2012 **Judy Maro, PhD**, MIT Engineer Systems Division
Served on Judy's PhD committee as content expert, published one manuscript and assisting with funding opportunities; thesis is titled: "Examining Value of Information Analysis in Medical Product Decisions."

2012-2013 **Laura Garabedian, PhD candidate in Health Policy**, Harvard University
Lead faculty mentor in a study of the unintended consequences of health insurance mandates and exchanges. Study focuses on the high-cost, short-term enrollment in MA after health reform.

2012 **Genu Buonaccorsi, MPH**, Tufts University
Mentor and advisor for an on-site internship focusing on the impact of FDA regulatory actions on the use of long-acting beta-agonist (LABAs).

2012-2013 **Max Ehrmann, MPH**, Columbia University
Mentor, advisor, and 2nd reader for Master's thesis focusing on the utility of rapid-response parameterized queries for drug safety surveillance.

Post-doctoral

2011-2014 **Amol Navathe, MD, PhD**, Harvard Medical School
Served as junior mentor at Department of Population Medicine. Amol is a Clinical Fellow at Harvard Medical School and physician at Brigham and Women's Hospital and Harvard Vanguard Medical Associates in Boston, MA, and Adjunct Senior Fellow at the Leonard Davis Institute of Health Economics at The Wharton School, University of Pennsylvania.

2012-2013 **Judy Maro, PhD**
Mentor for Judy's Post-doctoral Fellowship.

2014-2021 **Catherine Panozzo, PhD**
Departmental mentor
Current position: Assistant professor, Harvard Medical School and Harvard Pilgrim Health Care Institute

2014-2017 **Judy Maro, PhD**
Departmental mentor
Current position: Assistant professor, Harvard Medical School and Harvard Pilgrim Health Care Institute

2019- **Young Hee Nam, PhD**
Mentor
Post-doctoral Fellow, Harvard Medical School and Harvard Pilgrim Health Care Institute

2019- **Jane Huang, PhD**
Mentor
Current position: Research Scientist, Harvard Medical School and Harvard Pilgrim Health Care Institute

Report of Local Invited Presentations

Presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.

2006 **How to use large databases for therapeutics research: Examples, technical and practical considerations**
Seminar
Drug Policy Research Group, Ambulatory Care and Prevention, Harvard Medical School

2006 **Pharmaceutical pricing and payment in the US**
Seminar
Drug Policy Research Group, Medicines and Insurance Coverage Working Group, Ambulatory Care and Prevention, Harvard Medical School

2009 **Demonstration of distributed querying: AHRQ's Distributed Research Network: applications to public health surveillance**
Invited Lecture
Harvard Public Health Informatics Center of Excellence, Boston, MA

2015 **Overview of the FDA Mini-Sentinel Active Surveillance System**
Invited Lecture
Tufts University, Tufts Medical Center Institute for Clinical Research and Health Policy Studies, Boston, MA

2017 **Sentinel's modular programs and their effect on transparency and standardization of database analytics**
Invited Lecture

Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics (DoPE), Boston, MA

2017 **Use of Electronic Health Care Data for Evidence Generation**
Grand Rounds
Division of General Medicine and Primary Care Grand Rounds, Beth Israel Deaconess Medical Center, Boston, MA

2017 **Overview of FDA Sentinel and Opportunities to Collaborate**
Invited Lecture
Institute for Clinical and Economic Review
Boston, MA

Report of Regional Invited Teaching and Presentations

Presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.

2008 **Safety surveillance - Translating knowledge from other industries: Provider and researcher perspective**
Panelist
Center for Biomedical Innovation, Massachusetts Institute of Technology, Cambridge, MA

2010 **Current topics in drug safety surveillance**
Invited Lecture
Drug Safety and Risk Management, Biogen Idec, Boston, MA

2011 **Overview of the Mini-Sentinel project**
Invited Lecture
Partners Health Care Clinical Informatics R&D, Wellesley, MA

2011 **Multi-Center Studies in Pharmacoepidemiology**
Invited Lecture
Department of Epidemiology, University of North Carolina, Chapel Hill, NC

2011 **Update on the FDA Mini-Sentinel Project**
Invited Lecture
Drug Safety and Risk Management, Biogen Idec, Boston, MA

2013 **Multi-Center Studies in Pharmacoepidemiology**
Invited Lecture
Department of Epidemiology, University of North Carolina, Chapel Hill, NC

2013 **The MDPHnet Distributed Querying Approach for Public Health**
Invited Lecture
Promoting Prevention in Medicaid and CHIP, Using health IT to improve access to preventive services, Centers for Medicare and Medicaid Services (webinar)

2013 **Update on the FDA Mini-Sentinel Program**
Invited Lecture
Center for Biomedical Innovation, New Drug Development Paradigms Initiative (NEWDIGS), Massachusetts Institute of Technology, Cambridge, MA

2014 **Overview of FDA Mini-Sentinel and Prospective Routine Medical Product Safety Surveillance**
Panelist
New England Statistical Symposium, Harvard School of Public Health, Boston, MA

2014 **FDA Mini-Sentinel System: Use Case of On Market Data Initiatives**
Invited Lecture
Center for Biomedical Innovation, New Drug Development Paradigms Initiative (NEWDIGS), Massachusetts Institute of Technology, Cambridge, MA

2014 **FDA Mini-Sentinel System**
Invited Lecture
HSPH Lecture, Boston, MA

2015 **FDA Mini-Sentinel System: Lessons learned for other distributed networks**
Invited Lecture
Center for Biomedical Innovation, New Drug Development Paradigms Initiative (NEWDIGS), Massachusetts Institute of Technology, Cambridge, MA

2017 **Recent Developments and Future Perspectives on Data Distributed Network Systems including Sentinel, PCORnet and BBCIC**
Invited Lecture
Pfizer, Inc. New York, NY

2017 **Overview of the FDA Sentinel System and potential new uses**
Invited Lecture
Institute for Clinical and Economic Review Annual Policy Meeting – "Using Real World Evidence in Coverage Decisions: Realizing Potential or Generating Problems?" Phoenix, AZ

2017 **Distributed Health Data Networks: Pragmatism as the road to success**
Invited Lecture
11th Annual MIT Chief Data Officer and Information Quality Symposium
Cambridge, MA

2018 **Use of electronic healthcare databases in health services research**
Invited Lecture
Wellesley College
Wellesley, MA

2018 **The Ultimate Database for Outcomes Research - Essential Elements from Academia to the FDA & PCORI**
Invited Lecture
United Rheumatology's Normalized Integrated Community Evidence & Health Information Technology Platform Community Advisory Group
New York, NY

2021 **Health Data: From Data to Knowledge to Practice**
Speaker and Panelist
HIMSS Northern California ePatient Summit
Virtual

Report of National Invited Teaching and Presentations

Presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.

2006 **Detection of adverse drug events using maximized sequential probability ratio testing: Application in the HMO Research Network**
Invited Lecture
Centers for Education and Research on Therapeutics (CERTs) National Steering Committee, Washington, DC

2007 **Understanding drug safety through active surveillance**
Invited Lecture
University of California, San Francisco, American Course on Drug Development and Regulatory Sciences, Washington, DC

2007 **Creating distributed research networks for drug and vaccine safety studies: Issues and opportunities**
Invited Lecture
Food and Drug Administration, Office of Surveillance and Epidemiology, Rockville, MD

2008, 2009 **Use of summary counters with health plan data**
Seminar
HMO Research Network, Cancer Research Network, Webinar

2009 **Active drug safety surveillance and data mining**
Invited Lecture
University of Pennsylvania School of Medicine, Center for Clinical Epidemiology and Biostatistics, Philadelphia, PA

2009 **Signal detection and drug safety research with very large health care databases: Active drug safety surveillance and data mining**
Invited Lecture
American Society for Clinical Pharmacology and Therapeutics, Charlotte, NC

2009 **Multi-institutional studies using observational data: Opportunities and challenges**
Invited Lecture
Midwest Biopharmaceutical Statistics Workshop, Muncie, IN

2009 **Active drug safety surveillance using sequential methods**
Invited Lecture/HealthCore, Inc.
HealthCore, Inc., Wilmington, DE

2009 **Developing a distributed research network and cooperative to conduct population-based studies and safety surveillance: Distributed research network prototype and technology roadmap**
Selected oral abstract
HMO Research Network Annual Conference, Danville, PA

2009 **Developing a distributed research network and cooperative to conduct population-based studies and safety surveillance: System Architecture**
Selected oral abstract
HMO Research Network Annual Conference, Danville, PA

2009 **Building and evaluating a network proof-of-principle to demonstrate selected functions of a distributed research network**
Selected oral abstract
Agency for Healthcare Research and Quality, Clinical and Comparative Effectiveness Research Methods Symposium, Washington, DC

2009 **Active drug safety surveillance and data mining**
Invited Lecture/Pfizer Inc.
Pfizer, Inc., Data Mining Seminar Series, New York City, NY

2009 **Live demonstration of distributed querying: AHRQ's Distributed Research Network**
Invited Lecture
NIH CTSA Informatics Data Sharing Frameworks Working Group, Washington, DC

2009 **Informatics Opportunities and Challenges for Improving Drug Safety**
Panelist
American Medical Informatics Association Annual Conference, San Francisco, CA

2009 **Distributed research experience with the HMO Research Network and large health plans**
Invited Lecture and Panelist
Brookings Institute, Distributed Data Networks for Active Medical Product Surveillance: Expert Think Tank, Washington, DC

2009 **Demonstration of distributed querying: AHRQ's Distributed Research Network**
Invited Lecture
Centers for Education and Research on Therapeutics National Steering Committee, Washington, DC

2010 **Defining and evaluating possible database models to implement the Sentinel Initiative**
Invited Lecture
Brookings Institute, Second Annual FDA Sentinel Initiative Public Workshop, Washington, DC

2010 **Design of a Distributed Data Network for Comparative Effectiveness Research**
Selected oral abstract
HMO Research Network annual conference, Austin, TX

2010 **Multi-Institutional Observational Studies for Addressing Rare Outcomes: Opportunities and Challenges**
Invited Lecture
American College of Clinical Pharmacology Spring Practice and Research Forum, Charlotte, NC

2010 **Creating a National Distributed Health Data Network**
Invited Lecture and Panelist
IOM's Roundtable on Value and Science-Driven Health Care: EHR Innovation Collaborative, Washington, DC

2010 **Creating a National Distributed Health Data Network: Lessons for Biobanking**
Invited Lecture and Panelist
Clinical Immunization Safety Assessment Bio-specimen Repository Meeting, Washington, DC

2010 A**n Example of Using the VDW: The HMORN Mini-Sentinel Program for the FDA**
Invited Lecture
Cancer Research Network Scholars Program, webinar

2010 **Overview of FDA's Mini-Sentinel Program**
Invited Lecture
Federal Partners Working Group, Washington, DC

2010 **Overview of the FDA mini-sentinel project and discussion of opportunities for cancer safety surveillance**

Invited Lecture
Cancer Research Network Steering Committee, webinar

2011 **Multi-Institutional Drug Safety Surveillance**
Invited Lecture
6th Annual Chapel Hill Drug Conference, Chapel Hill, NC

2011 **Drug Safety Data Mining With a Tree-Based Scan Statistic**
Selected oral abstract
HMO Research Network Annual Conference, Boston, MA

2011 **Use of Administrative Claims Data for CER: FDA's Mini-Sentinel Program - A Distributed Data Network to Assess Safety of Marketed Medical Products**
Panelist
AcademyHealth Annual Meeting, Washington, DC

2011 **Developing Better Evidence on Medical Product Safety**
Panelist
AcademyHealth Annual Meeting, Washington, DC

2011 **Spotlight Learning Series - Spotlight on Learning Health System: Building the Technical Infrastructure**
Invited Lecture
National eHealth Collaborative, NeHC University, webinar

2011 **ONC Summer Concert Series on Distributed Population Queries**
Invited Lecture
Office of the National Coordinator for Health Information Technology, webinar

2011 **FDA Sentinel Initiative Strategic Review: Mini-Sentinel Querying Capabilities and Lessons Learned from Recent Assessments**
Invited Lecture
Engelberg Center for Health Care Reform, Brookings Institute, Washington, DC

2011 **PopMedNet: Distributed Research Network Technologies for Population Medicine**
Invited Lecture
AcademyHealth Electronic Data Methods Forum for Comparative Effectiveness Research, Washington, DC

2011 **FDA Mini-Sentinel and the Common Data Model**
Invited Lecture
3rd Annual Great Lakes cGMP & Regulatory Science Forum, Chicago, IL

2011 **Development and Implementation of Distributed Health Data Networks: Lessons from Medical Product Safety, Public Heath Surveillance, and Comparative Effectiveness Research**
Selected oral abstract
American Medical Informatics Association Annual Symposium, Washington, DC

2011 **Designs and Implementations of Informatics Platforms for Comparative Effectiveness Research**
Panelist
American Medical Informatics Association Annual Symposium, Washington, DC

2011 **Development and Implementation of a Distributed Health Data Network**
Selected oral abstract
American Public Health Association Annual Meeting, Washington, DC

2011 **Secondary Data Use: Overview and Implications**
Invited Lecture
Privacy and Security Communities of Practice, Office of the National Coordinator for Health Information Technology, Washington, DC

2012 **FDA's Mini-Sentinel Program to Evaluate the Safety of Marketed Medical Products: A functioning distributed database and querying system.**
Invited Lecture
Institute Of Medicine, Digital Data Priorities For Continuous Learning In Health And Health Care, Washington, DC

2012 **Development and Implementation of Distributed Health Data Networks: Lessons from Medical Product Safety, Public Heath Surveillance, and Comparative Effectiveness Research**
Selected oral abstract
Bio-It World Conference and Expo, Boston, MA

2012 **FDA Mini-Sentinel Project**
Educational Symposium
World Drug Safety Conference, Rick Management Activities, Boston, MA

2012 **Bringing Data Closer to Investigators**
Selected oral abstract
HMO Research Network Annual Meeting, Boston, MA

2012 **Distributed Research Networks: Lessons from the Field**
Invited Lecture
The Learning Health System Summit, Joseph H. Kanter Family Foundation, Washington, DC

2012 **Distributed Health Data Research Networks**

Invited Lecture
University of Southern California, Leonard D. Schaeffer Center for Health Policy and Economics, Los Angeles, CA

2012 **The MDPHnet Distributed Querying Approach for Public Health**
Selected oral abstract
Open Source EHR Summit and Workshop, Washington, DC

2012 **Late Breaking Session - Realizing a National Learning Health System**
Panelist
American Medical Informatics Association Annual Symposium, Chicago, IL

2013 **Opportunities to Expand the Public Health Impact of the Sentinel Initiative**
Panelist
Brookings Institute, Fifth Annual Sentinel Initiative Public Workshop, Washington, DC

2013 **Lessons from Two Distributed Networks for Public Health**
Panelist
Public Health and the Learning Health System: A National Meeting, The Network for Public Health Law, Ann Arbor, MI

2013 **Pains and Palliation in Distributed Research Networks: Lessons from the Field**
Panelist
American Medical Informatics Association Annual Summit on Clinical Research Informatics, San Francisco, CA

2013 **Provider-Payer-Pharma Cross-Industry Data Collaboration: Overview of the Mini-Sentinel Program**
Panelist
Medical Informatics World Conference, Boston, MA

2013 **Query Health: Toward a Learning Health System**
Selected oral abstract
American Medical Informatics Association Annual Meeting, Washington, DC

2013 **Reviewing current landscape of existing data consortiums: How they are being used, what they uncover, how they function—the Mini-Sentinel example**
Invited Lecture
Academy of Managed Care Pharmacy, Task Force on Biosimilar Collective Intelligence Systems, Alexandria, VA

2014 **Overview of Enhancements Underway to Mini-Sentinel**
Panelist

Brookings Institute, Sixth Annual FDA Sentinel Initiative Public Workshop, Washington, DC

2014 **Using Big Data to Encourage Innovation in Health and Health Care Delivery**
Panelist
America's Health Insurance Plans, Roundtable, Washington, DC

2014 **Distributed Health Data Networks: Application to Public Health**
Invited Lecture
Application of Law to Public Health Information Pre-Conference Workshop, 2014 Public Health Law Conference, Atlanta, GA

2014 **Setting the Agenda: Population Health Monitoring and EHRs: MDPHnet**
Invited Lecture
NYC Department of Health and Mental Hygiene, New York City, NY

2015 **FDA Mini-Sentinel: Standardizing Data and Tools to Speed Research**
Panelist
Multisite Collaboration and Data, HMO Research Network VDW Operations Committee

2015 **PCORnet CDRN Data Quality Challenges and Solution**
Panelist
American Medical Informatics Association Annual Summit on Clinical Research Informatics, San Francisco, CA

2015 **Precision Medicine Initiative: Central versus Distributed Models**
Panelist
Workshop of the Precision Medicine Initiative Working Group of the Advisory Committee to the NIH Director, Nashville, TN

2015 **FDA Mini-Sentinel: Past, present, and future**
Panelist
Drug Information Association Annual Meeting, Washington, DC

2015 **Data Quality and Missing Data in Patient-Centered Outcomes Research using EMR/Claims data**
Panelist
PCORI Data Quality Working Group, PCORI, Washington, DC

2016 **Current and Future Development of the Sentinel System**
Panelist
Duke-Robert J. Margolis Center for Health Policy, Washington, DC

2016 **Using electronic health data to generate knowledge: So you're telling me there's a chance?**

Invited Talk/ Flatiron Health
Flatiron Health, New York City, NY

2016 **Real world research conducted through large scale data networks**
Invited Talk
GlaxoSmithKline (GSK), Collegeville, PA

2016 **Laying the Groundwork: A Sentinel / PRISM Overview**
Invited Talk
The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Public Workshop, Bethesda, MD

2016 **The Drug Development Paradigm in Oncology**
Panelist
National Cancer Policy Forum, Washington, DC

2017 **Is an Algorithm Just an Algorithm? How to Define Clinical Concepts for Use in Comparative Safety and Effectiveness Distributed Research Networks**
Panelist, Session Chair
American Medical Informatics Association (AMIA) Joint Summit, San Francisco, CA

2017 **Distributed querying across PCORnet: Early lessons**
Panelist, Session Chair
American Medical Informatics Association (AMIA) Joint Summit, San Francisco, CA

2017 **Existing Systems and Infrastructure for Clinical Networks And Operations For Threat Response – Advantages And Challenges**
Panelist
National Capability to Monitor and Assess Medical Countermeasure Use in Response to Public Health Emergencies: A Stand Alone Workshop, The National Academies of Science
Washington, DC

2017 **Distributed Health Data Networks: Pragmatism as the road to success**
Invited Talk, Panelist
Data Innovation: Implementing the Organization's Future Data Agenda: 11th Annual MIT Chief Data Officer and Information Quality Symposium, Cambridge, MA

2017 **BUILD, PCORnet & Sentinel: Background, Data Model and Data Elements Analyses from SENTINEL**
Invited Talk, Panelist
MDEpiNET RAPID Phase II / III Working Group Meeting
Washington, DC

2017 **IMEDS: A Public-Private Partnership to Facilitate Real World Evidence Generation Based on the FDA's Sentinel System**
Panelist
Drug Information Association Annual Meeting
Chicago, IL

2017 **Medical Product Safety Surveillance Research in Multi-site Settings**
Speaker and Panelist
FDA, Application of "Big Data" to Pediatric Safety Studies
Washington, DC

2017 **The PCORnet Learning Cycle**
Panelist
AMIA Annual Meeting
Washington, DC

2018 **The Use of Sentinel in Pediatric Safety**
Speaker and Panelist
FDA, Advancing Pediatric Pharmacovigilance
Washington, DC

2018 **IMEDS: A Collaboration based on the FDA's Sentinel Initiative**
Invited Lecture
DIA 2018
Boston, MA

2018 **Sentinel Update: Tools and Data**
Speaker and Panelist
Second Annual BBCIC Workshop
Alexandria, VA

2018 **Sentinel Rapid Refresh Cycle Project: BBCIC application**
Speaker and Panelist
Second Annual BBCIC Workshop
Alexandria, VA

2018 **Advancing Pediatric Pharmacovigilance**
Speaker and Panelist
ADEPT FDA
Silver Springs, MD

2019 **Unpacking Real-World Data Curation: Principles and Best Practices to Support Transparency and Quality**
Speaker and Panelist
Duke-Margolis Center for Health Policy

Washington, DC

2019 **Developing Real-World Data and Evidence to Support Regulatory Decision-Making**
Speaker and Panelist
Duke-Margolis Center for Health Policy
Washington, DC

2019 **New frontiers in STD-related pelvic inflammatory disease (PID), infertility, and other sequelae: Promise and Limitations of Observational Data and Data Networks in Defining the Reproductive Impact of PID in the United States**
Speaker and Panelist
Centers for Disease Control and Prevention
Atlanta, GA

2020 **Leveraging the Sentinel Initiative for COVID-19.**
Speaker and Panelist
Duke-Margolis Center for Health Policy, Twelfth Annual Sentinel Initiative Public Workshop
Virtual

2021 **Computable Phenotypes: A Primer on Creation, Evaluation and Applications**
Speaker and Panelist
American Medical Informatics Association (AMIA) 2021 Informatics Summit
Virtual

2021 **Using Real World Data in Research – Why and How?**
Speaker and Panelist
Friends of the National Library of Medicine, Real World Data and Electronic Health Records in Clinical Research Workshop
Virtual

2021 **Post Market Evidence Generation for Innovative Technologies**
Panelist
Duke-Margolis Center for Health Policy
Virtual

2021 **Coordinating COVID-19 Vaccines Evidence Development**
Panelist
Duke-Margolis Center for Health Policy and MITRE
Virtual

Report of International Invited Teaching and Presentations

Presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.

2004 **How can health-risk appraisal data contribute to cardiovascular outcomes research?**
Workshop
International Society for Pharmacoeconomics and Outcomes Research Annual Meeting, Arlington, VA

2004 **Cost-effectiveness of migraine prevention: Results from a model of topiramate treatment.**
Selected oral abstract
International Society for Pharmacoeconomics and Outcomes Research Annual Meeting, Arlington, VA

2004 **Using health-risk appraisal data for assessing predictors of hypertension treatment**
Selected oral abstract
International Society for Pharmacoeconomics and Outcomes Research Annual Meeting, Arlington, VA

2007 **Methodological considerations in conducting cost of illness studies employing large administrative claims databases**
Workshop
International Society for Pharmacoeconomics and Outcomes Research Annual Meeting, Arlington, VA

2008 **Sequential testing for signal detection**
Invited Lecture
International Society for Pharmacoepidemiology mid-year meeting, Boston, MA

2010 **Alternative Data Models & Maintaining Source Data Integrity: Lessons from multi-site programs and the Mini-Sentinel experience**
Invited Lecture
International Society for Pharmacoepidemiology mid-year meeting, Raleigh, NC

2010 **Designing and Using Distributed Networks**
Invited Lecture
Distributed Safety and Effectiveness Network (DSEN): DSEN Collaborative Innovation Forum on Research Methodologies in Real World Drug Safety and Comparative Effectiveness, Ottawa, CN

2011 **Developing Better Evidence for Product Safety**
Workshop
International Society for Pharmacoeconomics and Outcomes Research Annual Meeting, Baltimore, MD

2011 **Comparing Two Methods for Detecting Adverse Event Signals in Observational Data: Empirical Bayes Gamma Poisson Shrinker vs. Tree-Based Scan Statistic**
Selected oral abstract
27th International Conference on Pharmacoepidemiology &Therapeutic Risk Management, Chicago, IL

2011 **Addressing Challenges in Using Multiple Data Sources to Evaluate Medication Risk Factors for Asthma Mortality in Persistent Asthma**
Workshop
27th International Conference on Pharmacoepidemiology &Therapeutic Risk Management, Chicago, IL

2011 **Healthcare Databases: Harmonization of Data Across Multiple Resources**
Educational Symposium
27th International Conference on Pharmacoepidemiology &Therapeutic Risk Management, Chicago, IL

2012 **Distributed Electronic Health Data Networks for Medical Product Safety Surveillance**
Panelist
Drug Information Association Annual Meeting, Philadelphia, PA

2012 **Distributed Networks for Sentinel Surveillance**
Invited Lecture
BioMath, Feasibility study on the use of farmer/ producer associations/ federations to form sentinel surveillance networks: Workshop 1: Sentinel surveillance/ Existing networks/ systems for adverse event reporting. Webinar, Berlin, Germany

2013 **Data Mining Signal Detection in Longitudinal Databases**
Invited Lecture
Drug Safety Research Unit, 7th Biennial Conference On Signal Detection and Interpretation In Pharmacovigilance, London, England

2013 **DEBATE: What's the difference between signal generation, signal refinement and signal evaluation?**
Panelist
Drug Safety Research Unit, 7th Biennial Conference On Signal Detection and Interpretation In Pharmacovigilance, London, England

2013 **The Mini-Sentinel program**
Invited Lecture
International Society of Pharmacovigilance, 13th ISoP annual meeting, Pisa, Italy

2014 **FDA's Mini-Sentinel Program to Evaluate the Safety of Marketed Medical Products**
Invited Lecture
European Medicines Agency, Global Updates on Accelerated Access to Innovative Medicines for Patients in Need, London, England

2015 **Perspectives from the Health Domain and Biomedical Informatics: FDA Mini-Sentinel and other Distributed Networks**
Invited Lecture and Panelist
Building a Scientific Community for the Learning Health System Symposium at the 48th Hawaii International Conference on System Sciences (HICSS), Kauai, Hawaii

2015 **Big Data and Clinical & Research Data Integration in the LHS: Use of electronic health data to support a Learning Health System: Lessons from several distributed networks in the US**
Invited Lecture and Panelist
The Learning Health System in Europe Conference, Brussels, Belgium

2015 **Symposium: Generating Real-World Safety and Effectiveness Evidence for Biosimilars: Current Issues and Methodological Considerations**
Panelist
31st International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Boston, US

2015 **Rapid Cycle Analytics in Pharmacoepidemiology**
Panelist
31st International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Boston, US

2015 **Better Science, Better Health: New Healthcare Models. Learning from Other Data Sharing Initiatives**
Panelist
Center for Biomedical Innovation, New Drug Development Paradigms Initiative (NEWDIGS)
Massachusetts Institute of Technology, Washington, DC

2015 **Overview of the Mini-Sentinel Pilot: 6 Years of Progress and Challenges**
Invited Lecture
Saw Swee Hock School of Public Health, Singapore

2015 **Leveraging Electronic Health Records for Knowledge Generation**
Invited Lecture
Duke-National University of Singapore (NUS) Graduate Medical School, Health Services & Systems Research, Singapore

2015 **Building a National Public Health Surveillance System Using Electronic Health Data**
Invited Lecture
Ministry of Health, Health Science Authority, Singapore

2016 **Distributed data network architecture: Lessons from PCORnet and FDA Sentinel**
Invited Lecture
German Society for Medical Computer Science, Biometry and Epidemiology (GMDS) and the Technology, Methods, and Infrastructure for Networked Medical Research (TMF), Berlin, Germany

2017 **Optimizing Design, Conduct and Interpretation of EHR-enabled Randomised Clinical Trials: Case Examples Demonstrate the Critical Role of Epidemiology and Future Challenges**
Panelist
33rd International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Montreal, Canada

2017 **Real-World Battles With Real-World Data**
Panel Chair
33rd International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Montreal, Canada

2017 **Common Data Models to Support Rapid Evidence Generation in Distributed Networks**
Invited Lecture
Canadian Network for Observational Drug Effect Studies (CNODES), Montreal, Canada

2017 **Real World Battles with Real World Data**
Invited Lecture
33rd Annual International Conference for Pharmaco-Epidemiology
Montreal, Canada

2017 **Optimizing Design, Conduct, and Interpretation of HER-enabled Randomized Clinical Trials: Case Examples Demonstrate the Critical Role of Epidemiology and Future Challenges**
Invited Lecture
33rd Annual International Conference for Pharmaco-Epidemiology
Montreal, Canada

2017 **Taming the Kaleidoscope - Managing Change in RWD Studies**
Invited Lecture
33rd Annual International Conference for Pharmaco-Epidemiology
Montreal, Canada

2017 **Safety of Trumenba vaccine among pregnant women in the United States: Planning and design of a large-scale multi-site observational study**
Invited Lecture
33rd Annual International Conference for Pharmaco-Epidemiology
Montreal, Canada

2017 **Data Models for Evidence Generation**
Validation Approaches to Common Data Models
Invited Lectures
A Common Data Model for Europe? – Why? Which? How? European Medicines Agency, London, England

2017 **Common Data Models to Support Rapid Evidence Generation in Distributed Networks**
Invited Lecture
CNODES Semi-Annual Meeting
Quebec, Canada

2018 **Methods for Examining Data Quality in Healthcare**
Workshop
Pacific Symposium on Biocomputing 2018, The Big Island, Hawaii

2018 **Methods for Examining Data Quality in Healthcare Integrated Data Repositories**
Speaker and Panelist
Pacific Symposium in Biocomputing
The Big Island, Hawaii

2018 **International Comparison of Approaches to Common Data Models for Comparative Effectiveness Research**
Panel
International Population Data Linkage Network Conference 2018
Banff Centre, Banff, Alberta, Canada

2018 **Analytical Approaches to Distributed Data**
Panel
International Population Data Linkage Network Conference 2018
Banff Centre, Banff, Alberta, Canada

2018 **Using Electronic Health Data for Evidence Generation: From Research Networks to Pragmatic Trials to Population Surveillance**
Invited Lecture
RCSI General Practice and HRB Centre for Primary Care Research Royal College of Surgeons in Ireland
Dublin, Ireland

2018 **Big Data for Pharmacovigilance**
Invited Lecture
Royal College of Physicians
London, England

2018 **Data quality assessment and distributed analytics: Lessons from 10+ years of US distributed health data networks**
Invited Lecture
King's College London School of Population Health and Environmental Sciences
London, England

2019 **Infrastructure for RWE on Biologics and Biosimilar**
Invited Lecture
International Society for Pharmacoepidemiology 2019 Mid-Year meeting
Rome, Italy

2019 **Health Care Data Networks for Regulatory Policies**
Invited Lecture
Italian Medicines Agency (AIFA)
Rome, Italy

2019 **Signal detection in distributed health data networks in the US: Lessons, barriers, and opportunities**
Speaker and Panelist
ISPE's 12th Asian Conference on Pharmacoepidemiology
Kyoto, Japan

Report of Technological and Other Scientific Innovations

PopMedNet Software (2010 –) **www.popmednet.org**
Inventor and Chief Product Officer for an open-source software application – PopMedNet – that enables the creation, management, and operation of secure distributed research networks. The software architecture helped influence the approach adopted by the US Office of the National Coordinator for Health Information Technology's Standards & Interoperability Framework Query Health Initiative. PopMedNet is used by several large national networks funded by FDA, ONC, NIH, AHRQ, and PCORI.

ESPnet Software (2012 – 2016) **www.esphealth.org**
ESPnet combines two open source software systems, PopMedNet and EHR Support for Public Health (ESP). ESP is a disease surveillance software application use electronic health record data systems to identify events of public health importance. Integrating these technologies allows hospitals and clinics to give health departments controlled access to their EHR data to monitor health indicators and enable rapid querying of the EHR systems. ESPnet is being used by the Massachusetts Department of Public Health through their MDPHnet system.

FDA MyStudies Mobile App (2018 -)

www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app

The award-winning FDA MyStudies App is designed to facilitate the input of real world data directly by patients that can be linked to electronic health data supporting traditional clinical trials, pragmatic trials, observational studies and registries. The source code and technical documentation are available under an open-source license so the app and patient data storage system can be reconfigured by organizations conducting clinical research.

Report of Education of Patients and Service to the Community

Activities

1999 **Testimony before the Health Access Oversight Committee**
State of Vermont
Testimony regarding prescription drug prices and the market for prescription drugs in the United States.

Report of Scholarship

Peer-Reviewed Publications

Research Investigations

1. Bienz-Tadmor B, **Brown JS**. Biopharmaceuticals and conventional drugs: comparing development times. BioPharm. 1994;7(2):44-9.
2. Kaitin KI, **Brown JS**. A drug lag update. Drug Information Journal. 1995;29:361-73.
3. Shulman SR, **Brown JS**. The Food and Drug Administration's early access and fast-track approval initiatives: how have they worked? Food Drug Law J. 1995;50(4):503-31.
4. **Brown JS**, Bienz-Tadmor B, Lasagna L. Availability of anticancer drugs in the United States, Europe, and Japan from 1960 through 1991. Clin Pharmacol Ther. 1995;58(3):243-56.
5. DiMasi JA, **Brown JS**. An analysis of regulatory review times of supplemental indications for already-approved drugs: 1989 to 1993. Drug Information Journal. 1996;30(2):315-37.
6. **Brown JS**, Kaitin KI, McAuslane N, Thomas K, Walker SR. Population exposure required to assess clinical safety: a report to the International Conference on Harmonization Efficacy Working Group. Drug Information Journal. 1996;30(10):17-27.
7. Pegus C, Bazzarre TL, **Brown JS**, Menzin J. Effect of the Heart At Work program on awareness of risk factors, self-efficacy, and health behaviors. J Occup Environ Med. 2002;44(3):228-36.
8. Ross-Degnan D, Simoni-Wastila L, **Brown JS**, Gao X, Mah C, Cosler LE, Fanning T, Gallagher P, Salzman C, Shader RI, Inui TS, Soumerai SB. A controlled study of the effects of state surveillance on indicators of problematic and non-problematic benzodiazepine use in a Medicaid population. Int J Psychiatry Med. 2004;34(2):103-23.
9. Simoni-Wastila L, Ross-Degnan D, Mah C, Gao X, **Brown JS**, Cosler LE, Fanning T, Gallagher P, Salzman C, Soumerai SB. A retrospective data analysis of the impact of the New York triplicate prescription program on benzodiazepine use in medicaid

patients with chronic psychiatric and neurologic disorders. Clin Ther. 2004;26(2):322-36.

10. **Brown JS**, Papadopoulos G, Neumann PJ, Friedman M, Miller JD, Menzin J. Cost-effectiveness of topiramate in migraine prevention: results from a pharmacoeconomic model of topiramate treatment. Headache. 2005;45(8):1012-22.
11. **Brown JS**, Rupnow MF, Neumann P, Friedman M, Menzin J. Cost effectiveness of topiramate in the prevention of migraines in the United States: an update. Manag Care Interface. 2006;19(12):31-8.
12. **Brown JS**, Papadopoulos G, Neumann PJ, Price M, Friedman M, Menzin J. Cost-effectiveness of migraine prevention: the case of topiramate in the UK. Cephalalgia. 2006;26(12):1473-82.
13. Kazan-Tannus JF, Dialani V, Kataoka ML, Chiang G, Feldman HA, **Brown JS**, Levine D. MR volumetry of brain and CSF in fetuses referred for ventriculomegaly. AJR Am J Roentgenol. 2007;189(1):145-51.
14. Lieu TA, Kulldorff M, Davis RL, Lewis EM, Weintraub E, Yih K, Yin R, **Brown JS**, Platt R, Real-time vaccine safety surveillance for the early detection of adverse events. Med Care. 2007;45(10 Supl 2):S89-95.
15. **Brown JS**, Kulldorff M, Chan KA, Davis RL, Graham D, Pettus PT, Andrade SE, Raebel MA, Herrinton L, Roblin D, Boudreau D, Smith D, Gurwitz JH, Gunter MJ, Platt R. Early detection of adverse drug events within population-based health networks: application of sequential testing methods. Pharmacoepidemiol Drug Saf. 2007;16(12):1275-84.
16. Andrade SE, Raebel MA, **Brown JS**, Lane K, Livingston J, Boudreau D, Rolnick SJ, Roblin D, Smith DH, Willy ME, Staffa JA, Platt R. Use of antidepressant medications during pregnancy: a multisite study. Am J Obstet Gynecol. 2008;198(2):194.e-1-5.
17. **Brown JS**, Neumann PJ, Papadopoulos G, Ruoff G, Diamond M, Menzin J. Migraine frequency and health utilities: findings from a multi-site survey. Value in Health. 2008;11(2):315-21.
18. Andrade SE, Raebel MA, **Brown JS**, Lane K, Livingston J, Boudreau D, Rolnick SJ, Roblin D, Smith DH, Dal Pan GJ, Scott PE, Platt R. Outpatient use of cardiovascular drugs during pregnancy. Pharmacoepidemiol Drug Saf. 2008;17(3):240-7.
19. Moore KM, Duddy A, Braun MM, Platt R, **Brown JS**. Potential population-based electronic data sources for rapid pandemic influenza vaccine adverse event detection: a survey of health plans. Pharmacoepidemiol Drug Saf. 2008;17(12):1137-41.
20. Velentgas P, Bohn RL, **Brown JS**, Chan KA, Gladowski P, Holick CN, Kramer JM, Nakasato C, Spettell CM, Walker AM, Zhang F, Platt R. A distributed research network model for post-marketing safety studies: The Meningococcal Vaccine Study. Pharmacoepidemiol Drug Saf. 2008;17(12):1226-34.
21. **Brown JS**, Kulldorff M, Petronis KR, Reynolds R, Chan KA, Davis RL, Graham D, Andrade SE, Raebel MA, Herrinton L, Roblin D, Boudreau D, Smith D, Gurwitz JH, Gunter MJ, Platt R. Early adverse drug event signal detection within population-based health networks using sequential methods: key methodologic considerations. Pharmacoepidemiol Drug Saf. 2009;18(3):226-34.

22. **Brown JS,** Moore KM, Braun MM, Ziyadeh N, Chan KA, Lee GM, Kulldorff M, Walker AM, and Platt R. Active Influenza Vaccine Safety Surveillance: Potential Within a Healthcare Claims Environment. Med Care 2009;47(12):1251-7.
23. Moore KM, Duddy A, Lee GM, Velentgas P, Burwen DR, Platt R, **Brown JS**. Same-day influenza vaccine adverse event detection: limited predictive value of outpatient urticaria diagnosis codes. J Clin Epidemiol 2010;63(4):407-11.
24. Mapel DW, Schum M,Yood MU, **Brown JS**, Miller DP, Davis KJ. Pneumonia Among COPD patients using inhaled corticosteroids and long-acting bronchodilators. Prim Care Resp J, 2010 Jun;19(2):109-17.
25. **Brown JS**, Holmes JH, Shah K, Hall K, Lazarus R, Platt R. Distributed health data networks: a practical and preferred approach to multi-institutional evaluations of comparative effectiveness, safety, and quality of care. Med Care 2010; 48:S45-51.
26. Maro JC and **Brown JS.** Impact of exposure accrual on sequential postmarket evaluations: a simulation study. Pharmacoepidemiol Drug Saf. 2011;(11):1184-91.
27. Toh S, Platt R, Steiner JF, **Brown JS**. Comparative-effectiveness research in distributed health data networks. Clin Pharmacol Ther. 2011;90(6):883-7.
28. Curtis LH, Weiner MG, Boudreau DM, Cooper WO, Daniel GW, Nair VP, Raebel MA, Beaulieu NU, Rosofsky R, Woodworth TS and **Brown JS.** Design considerations, architecture, and use of the Mini-Sentinel distributed data system. Pharmacoepidemiol Drug Saf. 2012;21(S1): 23–31.
29. Platt R, Carnahan RM, **Brown JS**, Chrischilles E, Curtis LH, Hennessy S, Nelson JC, Racoosin JA, Robb M, Schneeweiss S, Toh S and Weiner MG. The U.S. Food and Drug Administration's Mini-Sentinel program: status and direction. Pharmacoepidemiol Drug Saf. 2012;21(S1): 1–8.
30. Hall GC, Sauer B, Bourke A, **Brown JS**, Reynolds MW, Casale RL. Guidelines for good database selection and use in pharmacoepidemiology research. Pharmacoepidemiol Drug Saf. 2012;21: 1–10.
31. Eichler HG, Oye K, Baird LG, Abadie E, **Brown JS**, Drum CL, Ferguson J, Garner S, Honig P, Hukkelhoven M, Lim J C W, Lim R, Lumpkin MM, Neil G, O'Rourke B, Pezalla E, Shoda D, Seyfert-Margolis V, Sigal EV, Sobotka J, Tan D, Unger TF and Hirsch G. Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval. Clin Pharmacol Ther. 2012;91(3):426-37.
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33. Velentgas P, Amato AA, Bohn RL, Arnold Chan K, Cochrane T, Funch DP, Dashevsky I, Duddy AL, Gladowski P, Greenberg SA, Kramer JM, McMahill-Walraven C, Nakasato C, Spettell CM, Syat BL, Wahl PM, Walker AM, Zhang F, **Brown JS**, Platt R. Risk of Guillain-Barré syndrome after meningococcal conjugate vaccination. Pharmacoepidemiol Drug Saf. 2012;21(12):1350-8
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sources to monitor H1N1 vaccine safety points to potential for even broader safety surveillance. Health Aff (Millwood). 2012 Nov;31(11):2518-27.

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39. Toh S, Gagne JJ, Rassen RA, Fireman BH, Kulldorff M, and **Brown JS**. Confounding adjustment in comparative effectiveness research conducted within distributed research networks. Med Care. 2013 Aug;51(8 Suppl 3):S4-S10.
40. Maro JC, **Brown JS**, Kulldorff M. Medical Product Safety Surveillance: How Many Databases to Use? Epidemiology 2013 Sep;24(5):692-9.
41. **Brown JS**, Kahn M, Toh S. Data quality assessment for comparative effectiveness research in distributed data networks. Med Care. 2013 Aug;51(8 Suppl 3):S22-9.
42. Kim SC, Gillet VG, Feldman S, Lii H, Toh S, **Brown JS**, Katz JN, Solomon DH, Schneeweiss S. Validation of claims-based algorithms for identification of high-grade cervical dysplasia and cervical cancer. Pharmacoepidemiol Drug Saf 2013 Nov;22(11):1239-44.
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44. Maro, JC, **Brown, JS**, Dal Pan, GJ and Kulldorff, M. Minimizing signal detection time in postmarket sequential analysis: balancing positive predictive value and sensitivity. Pharmacoepidemiol Drug Saf. 2014 Aug;23(8):839-48.
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49. Vogel J, Klompas M, **Brown JS**, Land T, and Platt R. MDPHnet: Secure, Distributed Sharing of Electronic Health Record Data for Public Health Surveillance, Evaluation, and Planning. American Journal of Public Health. 2014 Dec;0: e1-e6.
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51. Curtis LH, **Brown JS**, Platt R. Four Health Data Networks Illustrate The Potential For A Shared National Multipurpose Big-Data Network. Health Affairs, 33, no.7 (2014):1178-1186.
52. Friedman C, Rubin J, **Brown JS**, Buntin M, Corn M, Etheredge L, Gunter C, Musen M, Platt R, Stead W, Sullivan K, Van Houweling D. Toward a science of learning systems: a research agenda for the high-functioning Learning Health System. J Am Med Inform Assoc. 2015 Jan;22(1):43-50.
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55. AMCP Task Force on Biosimilar Collective Intelligence Systems, Baldziki M, **Brown JS**, Chan H, Cheetham TC, Conn T, Daniel GW, Hendrickson M, Hilbrich L, Johnson A, Miller SB, Moore T, Motheral B, Priddy SA, Raebel MA, Randhawa G, Surratt P, Walraven C, White TJ, Bruns K, Carden MJ, Dragovich C, Eichelberger B, Rosato E, Sega T. Utilizing data consortia to monitor safety and effectiveness of biosimilars and their innovator products. J Manag Care Spec Pharm. 2015 Jan;21(1):23-34. PubMed PMID: 25562770.
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Reviews, chapters, monographs, editorials, and reports

1. **Brown JS**, Moore KM, Duddy A, and Platt R. Instructional guide for implementing maxSPRT within a healthcare claims environment. Contract No. Report to the U.S. Food and Drug Administration, Contract No. HHSF223200710017C; February 2008.
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1. Zhang J, Haynes K, Mendelsohn AB, Marshall J, Barr CE, McDermott C, Kline A, Kenney J, King KJ, Holmes C, Yun H, Yeung K, Barron J, **Brown JS**, Lockhart CM. Capture of Biologic and Biosimilar Dispensings in a Consortium of U.S.-Based Claims

Databases - Utilization of National Drug Codes and HCPCS Modifiers in Medical Claims. 35th ICPE Meeting, 2019, Philadelphia, PA.

2. Malek S, King KJ, Lockhart CM, Mendelsohn AB, **Brown JS**. Perspectives from a Coordinating Center: Lessons learned from the Biologics and Biosimilars Collective Intelligence Consortium HCSRN Annual Meeting 2019, Portland, OR.
3. Barrett K, Malenfant J, Curtis L, George J, Kripalani S, Limper H, O'Brien E, Reece **Brown JS**. Evaluating the Concordance between Patient Reported Data and Electronic Health Record Data: A Scalable Query Interface for Complex Analysis. AMIA 2020 Informatics Summit, San Francisco, CA.
4. Wu A, McMahon PM, Mendelsohn A, Welch E, Gokhale M, McMahill-Walraven C, Zhang J, Jamal-Allial A, Gallagher M, Draper C, Kline A, Koerner L, **Brown JS**, Van Dyke M. Use of Mepolizumab among Individuals with Asthma in the US. American Thoracic Society 2020 Annual Meeting, Philadelphia, PA.
5. Lockhart CM, McDermott CL, Marshall J, Mendelsohn AB, Pawloski P, **Brown JS.** Longitudinal evaluation of characteristics, treatment patterns, and general outcomes among patients using granulocyte colony stimulating factors: a Biologics and Biosimilars Collective Intelligence Consortium study. NCCN Conference 2020, Orlando, FL.
6. McDermott CL, Marshall J, Mendelsohn AB, **Brown JS**, Lockhart CM. Longitudinal Evaluation of Product Utilization and Characteristics Among Patients Treated with Biologic Anti-Inflammatory Agents: A Study by the Biologics and Biosimilars Collective Intelligence Consortium. ISPOR 2020, Orlando, FL.
7. Nam YH, Mendelsohn AB, Marshall J, McDermott CL, **Brown JS**, Lockhart CM. Utilization Patterns and Characteristics of Patients Treated with the Originator and the Follow-on Insulin Glargine in the United States. AMCP Annual meeting 2021.

Narrative Report

My primary research activities involve new approaches to facilitate large-scale, multi-institutional research through use of distributed health data networks to support a learning health system. My research forms the basis for several established research networks, including the FDA's Sentinel System and the PCORI National Clinical Research Network (PCORnet), and similar research network projects underway across the globe. These electronic health data networks have issued thousands of distributed queries to support medical product safety, clinical effectiveness, and public health surveillance.

I am the Lead Data Scientist for Network Operations for the FDA Sentinel Operations Center and a member of the Sentinel Operations Center Executive Committee and Principal Investigator of the analytic coordinating centers for the Reagan-Udall Foundation's Innovation in Medical Evidence Development and Surveillance (IMEDS) program and the Academy of Managed Care Pharmacy's Biologics and Biosimilars Collective Intelligence Consortium (BBCIC). I am also PI of several industry-sponsored multi-site pharmacoepidemiologic studies to support FDA and EMA regulatory requirements.

Sentinel is multi-year project to operate a national surveillance system for monitoring the safety of FDA-regulated medical products. The project includes 17+ data partners with over 650 million person-years of data. Sentinel is the first system capable of supporting rapid response distributed querying on this scale to support regulatory decision-making. The Sentinel System has generated 200+ publications and results have informed multiple FDA health safety communications and medical product labeling changes and have been presented at several FDA Advisory Committee meetings.

I am the Inventor of PopMedNet™ (www.popmednet.org), an open-source software platform that enables creation, and operation of distributed health data networks. PopMedNet supports several multi-site research and surveillance projects. I lead the project team that created the award-inning FDA MyStudies app (https://www.fda.gov/drugs/science-and-research-drugs/fdas-mystudies-application-app) that has supported multiple studies in the collection of patient-reported information.

Prior to joining the HMS faculty in 2005, I spent 5 years conducting health economics and outcomes research for a small consulting company. My work focused on the adoption, diffusion, and impact of medical technologies. My original articles include assessments of patient-preferences and decision-analytic cost-effectiveness models.

In teaching, I contribute both locally and nationally. I have tutored in the Clinical Epidemiology and Population Health course for Harvard Medical School students and lectured a Bioinformatics course for the Center for Biomedical Informatics and for a Harvard Medical School Catalyst course in clinical research. I have mentored an HMS Clinical Fellow and PhD/ScD and MPH students at Harvard, Tufts, MIT, and Columbia. Within DPM, I serve as an advisor to faculty members interested in using observational data for research projects. I speak widely on approaches to facilitating multi-institutional research for drug and vaccine safety surveillance using electronic health data.

Administratively, I am a member of DPM's Therapeutics Research and Infectious Disease Epidemiology (TIDE) program Executive Committee, helping to oversee a staff of 125+ scientists, analysts and project managers.