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FDA Biologics Effectiveness and Safety (BEST) Initiative

The U.S. Food & Drug Administration (FDA) needs to make decisions on drug and vaccine safety and effectiveness with confidence. As a key collaborator on the FDA Biologics Effectiveness and Safety (BEST) Initiative, Optum Epidemiology applies rigorous methodology and operating standards to generate reproducible results that inform regulatory decisions for COVID-19 vaccines.

Providing evidence for regulatory decisions

The BEST Initiative aims to help the FDA Center for Biologics Evaluation and Research (CBER) conduct surveillance and epidemiologic studies by creating access to new methods, tools and sources of data.

The initiative pulls real-world data from multiple electronic health care sources, including claims, electronic health records (EHRs) and linked claims-EHR data. Optum supports the development of research studies, from defining objectives and identifying data sources to interpreting and communicating results.*

Prevention and treatment of COVID-19

Optum Epidemiology leverages our robust claims and EHR databases to generate evidence for regulatory decisions and to execute epidemiologic protocols, including those related to the COVID-19 vaccine. Our related work with the FDA includes:

- Developing novel pre-adjudicated claims database for real-time vaccine safety surveillance
- Performing data linkage between each state's Immunization Information Systems and Optum pre-adjudicated claims
- Conducting COVID-19 vaccine safety and effectiveness studies to help inform regulatory decisions
- Publicizing scientific findings

Key publication in *The Lancet*

Hui-Lee Wong, Mao Hu, Cindy Zhou, Patricia Lloyd, **Kandace Amend,** Daniel Beachler, Alex Secora, Cheryl McMahill-Walraven, Yun Lu, Yu Wu, **Rachel Ogilvie,** Christian Reich, Audrey Djibo, Zhiruo Wan, **John Seeger,** Sandia Akhtar, Yixin Jiao, Yoganand Chillarige, Rose Do, John Hornberger, Joyce Obidi, Richard Forshee, Azadeh Shoaibi, Steven Anderson. Risk of Myocarditis/Pericarditis Following COVID-19 mRNA Vaccination in the United States: A Cohort Study in Claims Databases. *The Lancet* 2022;399(10342):2191-2199.

* More information about the BEST Initiative available at bestinitiative.org

Optum presentations on FDA BEST

Optum Epidemiology authors are in bold.

Liz Bell, Cindy Zhou, Karen Schneider, Patricia Lloyd, Tainya Clarke, Grace Yang, **Michael Wilkinson, Kandace Amend,** Emily Myers, Steven Anderson, Azadeh Shoaibi, **John Seeger,** Hui-Lee Wong. *Combining COVID-19 Vaccine data from claims with data from immunization information systems (IIS) to address exposure Misclassification: An approach within the FDA Biologics Effectiveness and Safety (BEST) Initiative.*[2]

Rachel Ogilvie, Jennifer Song, Cindy Zhou, Patricia Lloyd, Hui-Lee Wong, Tainya Clarke, Azadeh Shoaibi, **Kandace Amend, John Seeger.** *Reduction in data lag using Optum pre-adjudicated health insurance claims.*[2]

John Seeger, Michele Jonsson Funk, Bradley Layton, Azadeh Shoaibi. *Considerations of misclassification and confounding on COVID-19 vaccine effectiveness studies – a vaccine SIG-endorsed symposium.*[2]

Keran Moll, Bradley Lufkin, Cindy Zhou, Chianti Shi, Kathryn Fingar, Shanlai Shangguan, Shayan Hobbi, Mao Hu, Minya Sheng, Cameron Joyce, Timothy Burrell, Yoganand Chillarige, Jeff Beers, Patrick Saunders-Hastings, Stella Muthuri, Kathryn Edwards, Steven Black, Jeff Kelman, Christian Reich, **Kandace Amend,** Daniel Beachler, **Rachel Ogilvie,** Alex Secora, **John Seeger,** Patricia Lloyd, Deborah Thompson, Rositsa Dimova, Joyce Obidi, Steve Anderson, Richard Forshee, Hui Lee Wong, Azadeh Shoaibi. *Background rates of adverse events of special interest for COVID-19 vaccine safety monitoring among adults in the United States.*[2]

Mao Hu, Yuhui Feng, Chianti Shi, Cindy Zhou, Hui Lee Wong, Yixin Jiao, Yoganand Chillarige, Patricia Lloyd, **Kandace Amend,** Daniel Beachler, Alex Secora, Anne Marie Kline, Tainya Clarke, **Rachel Ogilvie,** Christian Reich, Cheryl McMahill-Walraven, **John Seeger,** Steven Anderson, Azadeh Shoaibi. *Adjusting for data observation delay in near real-time safety surveillance of COVID-19 vaccines using administrative claims databases.*[2]

Connect with Optum Epidemiology

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Learn more about the BEST Initiative at bestinitiative.org

An example of the results produced as part of BEST:

Near real-time surveillance of Pfizer-BioNTech COVID-19 vaccines in 12 to 64 years in Optum pre-adjudicated claims[1]

Adverse events of special interest	Risk window (days)	Safety signal during testing
Acute myocardial infarction	1-28	No
Anaphylaxis	0-1	Yes
Appendicitis	1-42	No
Bell's palsy	1-42	No
Common thromboses with thrombocytopenia	1-28	No
Unusual site thromboses with thrombocytopenia	1-28	No
Deep vein thrombosis	1-28	No
Disseminated intravascular coagulation	1-28	No
Encephalomyelitis	1-42	No
Guillain-Barré Syndrome	1-42	No
Hemorrhagic stroke	1-28	No
Immune thrombocytopenia	1-42	No
Multisystem inflammatory syndrome	1-42	No
Myocarditis and pericarditis	1-42	No
Narcolepsy	1-42	No
Non-hemorrhagic stroke	1-28	No
Pulmonary embolism	1-28	No
Transverse myelitis	1-42	No

1. Data through September 18, 2021. Adapted from Wong 2021.Post-Market Active Surveillance of COVID-19 in the Pediatric Population in the FDA BEST System. HYPERLINK "http://www.fda.gov/media/153511/download" www.fda.gov/media/153511/download
2. *Pharmacoepidemiology and Drug Safety* 2022; 31(S1).

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