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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 FDA Biologics Effectiveness and Safety (BEST) Initiative, Optum Epidemiology applies rigorous methodology and operating standards to generate reproducible results that inform regulatory decisions for 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.[1]

Optum Epidemiology contributions on FDA BEST

We leverage our robust claims and EHR databases to execute epidemiologic protocols, and generate evidence for regulatory decisions related to vaccine use. Our related work with the FDA includes:

- Developing a novel pre-adjudicated claims database for real-time vaccine safety surveillance
- Performing data linkage between state Immunization Information Systems and Optum pre-adjudicated claims to supplement vaccine exposure data
- Performing data linkage of administrative claims for pregnancies and infants
- Conducting vaccine safety and effectiveness studies to help inform regulatory decisions
- Publicizing scientific findings

Sequential testing results by health outcome following BNT162b2 primary series doses for health plan members aged 5 to 17 years in Optum[2]

Age group, y	No. of doses	Outcomes, No.	Person-time, d	RR
Anaphylaxis				
5-11	680 186	0	1 348 722	0.00
12-15	669 816	<11	1 337 763	5.50
16-17	337 391	<11	673 972	3.95
Appendicitis				
5-11	572 135	48	18 187 457	0.70
12-15	565 049	87	18 251 418	0.94
16-17	285 726	47	9 336 794	0.89
Bell palsy				
5-11	635 935	<11	20 175 890	0.53
12-15	615 692	11	19 893 989	0.57
16-17	308 945	<11	10 096 665	0.84
Common thromboses with thrombocytopenia				
5-11	572 768	0	14 156 025	0.00
12-15	566 008	0	14 069 963	0.00
16-17	286 191	0	7 151 741	0.00
Deep vein thrombosis				
5-11	572 759	0	14 155 801	0.00
12-15	565 957	0	14 068 697	0.00
16-17	286 133	<11	7 150 307	0.34
Disseminated intravascular coagulation				
5-11	572 773	0	14 102 730	0.00
12-15	566 010	0	14 053 504	0.00
16-17	286 198	0	7 144 258	0.00
Encephalitis or encephalomyelitis				
5-11	636 003	0	20 177 981	0.00
12-15	615 778	<11	19 896 658	0.62
16-17	308 985	0	10 097 982	0.00

1. More information about the BEST Initiative available at bestinitiative.org.
2. Data through June 25, 2022. Safety of the BNT162b2 COVID-19 vaccine in children aged 5 to 17 years. *JAMA Pediatrics*. Published online May 22, 2023.

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Optum co-authored publications for BEST

Optum Epidemiology authors are in bold.

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

Patricia Lloyd, Mao Hu, Hui-Lee Wong, Azadeh Shoaibi, Cindy Zhou, An-Chi Lo, **Kandace Amend**, Daniel Beachler, Cheryl McMahill-Walraven, Elizabeth Smith, **John D. Seeger**, Alex Secora, Audrey Djibo, Joyce Obidi, Yuhui Feng, **Jennifer Song**, Christian Reich, Charalynn Harris, Sandia Akhtar, **Robin Clifford**, Nandini Selvam, Jennifer Pigoga, Yixin Jiao, Yoganand Chillarige, Thomas MaCurdy, Richard Forshee, Steven Anderson. Near Real-Time Surveillance of Safety Outcomes in U.S. COVID-19 Vaccine Recipients aged 12 to 64 years. *Vaccine*. 2022; 40(45):6481-6488.

Keran Moll, Bradley Lufkin, Kathryn Fingar, Cindy K. Zhou, Ellen Tworkoski, Chianti Shi, Shayan Hobbi, Mao Hu, Minya Sheng, Jillian McCarty, Shanlai Shangguan, Timothy Burrell, Yoganand Chillarige, Jeff Beers, Patrick Saunders-Hastings, Kathryn Edwards, Stella Muthuri, Steven Black, Jeff Kelman, Christian Reich, **Kandace L. Amend**, Aubrey Djibo, Daniel Beachler, **Rachel P. Ogilvie**, Alex Secora, CN McMahill-Walraven, **John D. Seeger**, Patricia Lloyd, Deborah Thompson, Rose Dimova, Thomas MaCurdy, Joyce Obidi, Steven A. Anderson, Richard Forshee, Hui-Lee Wong, Azadeh Shoaibi. Background Rates of Adverse Events of Special Interest for COVID-19 Vaccine Safety Monitoring in the United States, 2019–2020. *Vaccine*. 2023; 41(2):333-353.

Karen L. Schneider, **Elizabeth J. Bell**, Cindy K. Zhou, Grace Yang, Patricia Lloyd, Tainya C. Clarke, **Michael Wilkinson**, Emily E. Myers, **Kandace L. Amend**, **John D. Seeger**, Yoganand Chillarige, Richard Forshee, Azadeh Shoaibi, Steven A. Anderson, Hui-Lee Wong. Immunization Information Systems to Improve Ascertainment of COVID-19 Vaccinations for Claims-based Vaccine Safety and Effectiveness Studies. *JAMA Network Open*. 2023;6(5):e2313512.

Mao Hu, Hui Lee Wong, Yuhui Feng, Patricia C. Lloyd, Elizabeth R. Smith, **Kandace L. Amend**, Annemarie Kline, Daniel C. Beachler, Joann F. Gruber, Mahasweta Mitra, **John D. Seeger**, Charlalynn Harris, Alex Secora, Joyce Obidi, Jing Wang, **Jennifer Song**, Cheryl N. McMahill-Walraven, Christian Reich, Rowan McEvoy, Rose Do, Yoganand Chillarige, **Robin Clifford**, Danielle D Cooper, Azadeh Shoaibi, Richard Forshee, Steven A. Anderson. Safety of the BNT162b2 COVID-19 Vaccine in Children Aged 5 to 17 Years. *JAMA Pediatr*. 2023 Jul 1;177(7):710-717.

Connect with Optum Epidemiology

John D. Seeger, PharmD, DrPH
Chief Scientific Officer, Epidemiology
john.seeger@optum.com

Florence T. Wang, ScD
Vice President, Epidemiology
florence.wang@optum.com

Optum.com/Epidemiology
Learn more about the BEST Initiative at bestinitiative.org

Sequential testing results by health outcome following BNT162b2 primary series doses for health plan members aged 5 to 17 years in Optum[2] (continued).

Age group, y	No. of doses	Outcomes, No.	Person-time, d	RR
Immune thrombocytopenia				
5-11	572 717	<11	18 205 909	1.49
12-15	565 907	<11	18 279 130	0.85
16-17	286 147	<11	9 350 455	0.60
Myocarditis or pericarditis 1- to 21-d Risk window, all settings				
5-11	572 742	<11	11 698 334	4.35
12-15	565 967	35	11 700 690	10.19[a]
16-17	286 151	13	5 912 687	3.47[a]
Narcolepsy				
5-11	572 762	0	18 207 458	0.00
12-15	565 952	<11	18 280 657	0.76
16-17	286 088	<11	9 348 810	0.60
Nonhemorrhagic stroke				
5-11	572 772	0	14 156 125	0.00
12-15	566 004	0	14 069 866	0.00
16-17	286 197	<11	7 151 916	0.99
Pulmonary embolism				
5-11	572 776	0	14 156 230	0.00
12-15	566 002	<11	14 069 828	0.56
16-17	286 159	0	7 150 951	0.00

Abbreviations: RR, rate ratio.

[a]Indicates a safety signal was observed for the health outcome in the data.

2. Data through June 25, 2022. Safety of the BNT162b2 COVID-19 vaccine in children aged 5 to 17 years. *JAMA Pediatrics*. Published online May 22, 2023.

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