



LUIS JÓDAR, Ph.D.

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SENIOR VICEPRESIDENT AND CHIEF MEDICAL OFFICER

VACCINE AND INFECTIOUS DISEASES R&D | CLINICAL TRIALS | MEDICAL AFFAIRS | RWE AND EPIDEMIOLOGY |
REGULATORY STRATEGY | PRODUCT & BUSINESS DEVELOPMENT | INTERNATIONAL HEALTH | OUTCOMES RESEARCH
| VACCINES POLICY & CORPORATE AFFAIRS | PUBLIC & PRIVATE PARTNERSHIPS | PROGRAM DEVELOPMENT |
PORTFOLIO INVESTMENT MANAGEMENT

Global SVP and Chief Medical Officer with over 25 years of vaccines/infectious diseases and Real World Evidence experience in leadership positions at Wyeth, Pfizer Inc. and in academic and international public sectors, including the International Vaccines Institute in Seoul, the World Health Organization, and the European Commission.

World Renowned Subject Matter Expert

Trained as a Ph.D neuroimmunologist and public health in Spain and Japan and recognized globally for in-depth expertise in vaccines/infectious diseases, RWE and epidemiological research, clinical development & regulatory sciences, portfolio management and investment decisions, and driving policy decisions on disease prevention/treatment and significant improvements in public health in over 50 countries. Global expert with numerous accreditations, certifications and over 130 publications in most prestigious peer-reviewed journals. Awarded the "Officer Cross of the Order of Civil Merit" from the King of Spain for his work on vaccines and vaccination programs in developing countries and Doctor of Science honoris causa, Drew University. Recipient of multiple grants including the development, registration and introduction of a serogroup A meningococcal vaccine in the Epidemic belt countries of sub-Saharan Africa to WHO/PATH, funded by the Bill and Melinda Gates Foundation.

Leadership, Management & Partnerships

A dynamic, forward thinking leader providing expertise, management, and experience on, scientific R&D, clinical, regulatory, Real-World Evidence, medical affairs, investment analysis and decisions, product valuation and policy matters related to vaccine/antivirals development, clinical evaluation, approval, and access. Leads the medical group for Vaccines and antivirals r with more than 180 colleagues with multidisciplinary expertise. Conduct observational/low-interventional and pragmatic clinical studies for over 40 assets to accelerate clinical development programs, expand label indications or increase access with over 150 publications per year. Multidisciplinary infrastructure gathering vaccinologists, infectious diseases pediatricians, immunologists, clinical epidemiologists, clinical operations, biostatisticians, and data analysts. Manages complex portfolios, review candidate valuations and make investment decisions on candidate products post POC to licensure and launch. Forges global partnerships and collaborates with organizations worldwide, including key vaccine policy committees, governments and elected officials, health professionals, academia, vaccines manufacturers, global agencies, development partners, and the private sector to advance scientific research, clinical development programs, licensure and launch vaccination programs to help prevent and control major infectious diseases. A recognized industry leader advancing global policies and best practices for clinical/regulatory, medical affairs and RWE, vaccine development, safety, business development, portfolio investment and immunization programs. Develops and manages relationships with external partners, which has helped secure critical funding for the development of vaccines and immunization programs globally.

EXPERIENCE

PFIZER INC. -

May 2008 – Present

Senior Vice President & Chief Medical Officer, Vaccines (2012-2022) and also for Vaccines/Antivirals (2022 – present)

- **Leadership:** Serve as the head of the Medical Organization for Pfizer's Vaccines and Antivirals with global strategic and portfolio investment responsibilities for Pfizer's vaccine and antivirals portfolio for multiple assets in development and marketed.
- **Real World Evidence:** leads the Real-World Evidence Organization for all Pfizer's portfolio including vaccines and infectious diseases. With over 150 clinical epidemiologists, clinical operations, biostatistics, data analysts, pharmacoepidemiologists and project managers, the organization is responsible for designing, conducting and analyzing data from observational, voluntaryPASS, low-interventional, pragmatic & label enhancement/expansion and hybrid RWE / RCT interventional trials across the organization end-to-end.
- **Medical Affairs:** leads the Vaccines/Antivirals medical affairs groups globally, regionally and at the country level.

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- **Clinical Development & Regulatory Approvals:** Lead global strategies as a member of Pfizer's senior-level vaccines/anti-infectives governance committees to drive portfolio analysis, investment decisions and the clinical development and regulatory approvals of new vaccines/antivirals globally:
 - Comirnaty®, an mRNA-based COVID-19 vaccine co-developed with Biontech, approved and introduced globally to tackle the COVID-19 global pandemic (continuous strain changes to adapt to circulating strains)
 - Paxlovid®, a protease inhibitor licensed for the treatment of COVID-19 infected individuals at risk of hospitalization and death
 - Prevnar 20® and Prevnar 13®, a multi-valent pneumococcal conjugate vaccines, developed for the prevention of IPD, Pneumonia and AOM caused by the serotypes included in the vaccines in both infants, children and adults
 - Abrysvo® apre-fusion F protein vaccine developed against RSV associated LRTI for use both in adults and for maternal immunization to protect newborns up to six months
 - Trumenba®, a serogroup B meningococcal vaccine, in adolescents.
 - NeisVac-C™ and Nimenrix™, serogroup C and serogroups ACWY meningococcal disease vaccines respectively, in routine infant immunization, toddler and adolescent vaccination programs worldwide.
 - FSME™, Tick-borne encephalitis vaccine, in endemic areas.
 - Pembraya™, a serogroup A, B, C, Y and W-135 meningococcal vaccine for use in adolescents
 - In development: S. aureus (terminated), C. difficile, Lyme disease (in partnership with Valneva), Group B Streptococcus (GBS), RSV antiviral, multiple mRNA-based vaccines against respiratory infections. Also a large portfolio of antivirals and monoclonal antibodies against respiratory infections
- **Investment Management:** manages a complex vaccine/antivirals portfolio making decisions using valuation metrics, to inform investment decisions to the value and impact of new vaccines. Focus on internal and external investment opportunities that are aligned with Pfizer's corporate strategic approach.
- **Strategic Planning:** Drive strategic vaccines initiatives, creating dramatic improvements in operational effectiveness and efficiency. Set the vision, mission, and direction of Pfizer's vaccines medical and scientific strategic plan.
- **Regulatory Strategy:** in-depth knowledge of regulatory sciences, devise and implement diverse regulatory pathways for rapid product approvals, serving as one of the main contacts for clinical and regulatory interactions to FDA, EMA, PMDA and other regulatory authorities.
- **Market Access:** Lead the generation and dissemination of scientific and clinical evidence to external stakeholders that demonstrate the need, value and impact of vaccine immunization programs for infants, adolescents and adults, ultimately preventing hundreds of thousands of deaths and disabilities globally.
- **Policy Development:** Play a key role in creating and supporting health policies by leading and conducting research and providing scientific advice to key stakeholders.
- **Partnerships:** Forge global partnerships with key health organizations, including WHO, UNICEF, Bill & Melinda Gates Foundation, BARDA, CEPI and Vaccine Technical Committees worldwide CDC/ACIP, JCVI, and STIKO.
- **Team Leadership:** Build and manage a large team of highly qualified vaccinologists, infectious diseases physicians, clinical scientists, program managers, clinical epidemiologists and data analysts and statisticians at the global level and medical managers at the regional and country levels. A large group of RWE scientists covering all the other therapeutic areas from Pfizer

VP and Head of Vaccines Medical Affairs in Emerging Markets (May 2010-April 2012); Executive Director, International Clinical and Scientific Affairs, Asia Pacific Wyeth Vaccines (May 2008-May 2010)

- **Medical Strategy and Implementation:** Led the design, management and execution of all vaccine-related medical strategy/plans and studies including epidemiological, clinical studies, post-registration effectiveness and outcomes research in emerging markets.

THE INTERNATIONAL VACCINE INSTITUTE - Seoul, South Korea

2002-2008

Deputy Director General, Vaccines Translational Research, and Adjunct Professor, Seoul National University, College of Medicine and School of Public Health

- **Global Real World Evidence Research:** Oversaw a multidisciplinary vaccine-related research agenda in more than 20 countries in Asia, Latin America and Africa, including pre- and post-licensure clinical trials, epidemiological prospective and

retrospective studies, socio-behavioural and economic studies of vaccine introduction, and policy research on vaccines against cholera, typhoid fever, shigellosis, rotavirus, Japanese encephalitis, *Haemophilus influenzae* b, and *Streptococcus pneumoniae*.

- **Global Clinical Studies:** Designed, conducted, and analysed Phase 1-4 studies for live and killed oral and parenteral subunit vaccines against cholera, shigella candidates and typhoid fever in several developing countries in Asia and Africa.
- **Product Development Partnerships:** Led product development partnerships and technology transfer initiatives for diarrheal diseases and flaviviruses (JE and Dengue). Focused on Emergent Biosolutions for an oral typhoid vaccine, AVANT immune-therapeutics for live oral cholera vaccine, Biofarma, Shantha, Vabiotech, Lanzhou for Vi- and WC-based cholera vaccines.
- **Financial Management:** Identified innovative financing mechanisms to fund the vaccination programs in the developing world including long-term sustainability of vaccination programs through cross subsidization strategies in six countries. Determined appropriate investments needed to develop new vaccines to prevent infectious diseases affecting the developing world.
- **Medical and Clinical Training:** Spearheaded training activities on vaccines and clinical trials throughout Asia-Pacific equipping immunization professionals with the skills and tools to evaluate and improve access to and delivery of vaccines.
- **Grants and Fund Raising:** Awarded grants (over 150 million US\$) from the Bill and Melinda Gates foundation, Wellcome Trust, NIH and Multilateral and Overseas Development Agencies.

THE WORLD HEALTH ORGANIZATION - Geneva, Switzerland

1996-2002

Head of Meningococcal Vaccines, Vaccine Research and Development/Quality Assurance and Safety of Biologicals, Department of Vaccines and Biologicals

- **Research and Development:** as head of meningococcal vaccines R&D, accelerated the introduction of vaccines against meningococcal meningitis through leading epidemiological surveillance, clinical development and introduction activities.
 - Led the Meningitis Vaccine Project which resulted in the design, development, technology transfer, production, evaluation, and implementation of a serogroup A meningococcal conjugate vaccine for use in the Meningitis Belt countries in sub-Saharan Africa. The vaccine produced by the Serum Institute of India (Meninfrivac®) positively impacted high-risk populations of around 200 million people across 18 African countries.
- **Vaccines and Biologicals Standardization and Control:** Established global vaccines standards against respiratory encapsulated bacteria:
 - Recommendations for quality control and production for group C meningococcal conjugate vaccines.
 - Standardization and validation of IgG ELISA to measure immune responses from pneumococcal conjugate vaccines.
 - Establishment of a threshold antibody level value to infer efficacy from immunogenicity data for pneumococcal conjugate vaccines.
- **Safety:** Advanced policies and practices related to adverse events through research, knowledge management and training activities.
 - Established the Global Vaccine Safety Advisory Committee to respond to vaccine-related adverse effects allegations.
 - Established the WHO Criteria for causality of adverse events following immunization.
- **Grants:** Helped the WHO receive the largest grant ever awarded for a single vaccine (the Meningitis Vaccine Project) with funding from the Bill and Melinda Gates Foundation.
- **Product development and Partnerships:** led a 70 USM\$ product development partnership between public laboratories (CBER), Clinical Research Organizations (Sync Biotech) and developing country producers (Serum Institute of India) for the development, technology transfer, clinical evaluation, licensure and introduction of a serogroup A meningococcal vaccine and for the development, evaluation and introduction of a meningococcal group B vaccine for epidemic control in New Zealand.
- **Global Surveillance and Clinical Trials:** Led WHO groups to develop epidemiological surveillance networks in Africa. Conducted clinical trials of new candidate vaccines against meningococcal disease, accelerated regulatory pathways of new vaccines against encapsulated respiratory bacteria, and designed introduction strategies for meningococcal conjugate vaccines with Ministers of Health from Africa and Middle-Eastern countries.

THE EUROPEAN COMMISSION- Brussels, Belgium

1995-1996

Scientific Officer Life Sciences and Technologies, Directorate General XII- Science, Research and Development

- **Neurosciences and immunology lead**
- **Vaccine R&D:** Spearheaded EU vaccine R&D priorities, inter-country collaboration and exchange of research and development opportunities. Facilitated networks of animal models for vaccine development and mucosal immunization.
- **Partnerships & Funding:** Drove effective partnerships among key European partners (European Parliament, Council of Ministers, European Vaccine Manufacturers and relevant public institutions in Member States) on Vaccines R&D strategies

resulting in the creation of the *Task force of Vaccines and Viral Diseases* with a six-fold budget increase compared to previous research initiatives.

- **Social & Technological Policy Analysis:** Initiated and led a prospective analysis of the European vaccines and biologicals market, industrial competitiveness vs. Japan and the US: Opportunities for technological development and impact on EU social policies.

OSAKA and NAGASAKI UNIVERSITIES- - Japan

1992-1995

Lecturer and Post-doctoral Researcher

- Neuroimmunology of opioid drugs
- Neurological pathways to long-term memory and synaptic plasticity

EDUCATION

Faculty of Pharmaceutical Sciences and Medicine, Universidad Complutense de Madrid, Spain

- PhD, Summa Cum Laude, Departments of Physiopathology, Faculty of Pharmacy and School of Public Health, Faculty of Medicine, (1990-1992)
- PharmD with Honors, specialized in clinical pharmacology Grade: A, Number 1 in years 1988/1989, 1989/1990 (1985-1990)

Other University Education:

- Diploma in Pharmaceutical Marketing (1988-1989)
- Bachelor's degree in Law, Universidad Nacional de Educación a Distancia (UNED) - Madrid, Spain (2nd year)-ongoing
- Diploma in Japanese language and culture. Osaka University of Foreign Studies, Osaka, Japan (1992)
- Diploma in Contemporary British history and political thought; Cambridge University, Cambridge, United Kingdom (1987)
- Diploma in History of Science and XIX and XX British literature. Cambridge University, Cambridge, United Kingdom (1989)

LICENSES, AWARDS, AND CERTIFICATIONS

- "Officer Cross of the Order of Civil Merit" from the King of Spain for work in vaccines and vaccination in developing countries
- Doctor in Science, Honoris Causa, Drew University, New Jersey, US
- Annual XVIII Premio COFNAVARRA recipient
- Post-doctoral fellowship of the Japanese Ministry of Culture - awarded to 10 Spanish PhDs from all fields (1992-1994)
- Post-Doctoral fellowship Japanese-German Berlin Centre - awarded to 30 European PhDs from all fields (1994-1995)
- International Civil Servant at the European Commission, DG XII (R&D) - achieved from 20,000 European PhD applicants.

EXTERNAL ROLES

Invited Lecturer/adjunct professor appointments in Vaccinology, infectious diseases, portfolio decision-making and Public Health

- Seoul National University, Schools of Medicine, Pharmacy and Biology, Seoul, South Korea
- International Advanced Vaccinology Course, Fondation Mérieux, Annecy, France
- Columbia University, New York City, USA
- Advanced Vaccinology Course, Institut Pasteur, France
- School of Public Health, Escuela de Salud Pública, Madrid, Spain
- Wharton School of Business, University of Pennsylvania, Philadelphia, USA

Ad-hoc Referee for peer-review journals:

- Lancet; Lancet ID; JID; Infection and Immunity; CID; EID; JID: The Bulletin of the World Health Organization; Biologicals; Vaccine

Multiple interviews in International newspapers, TV programs as Pfizer spokesperson

LANGUAGES

- Proficient in English, French and Japanese
- Spanish mother tongue

OVER 130 PUBLICATIONS AND BOOK CHAPTERS IN THE MOST RENOWNED PEER-REVIEWED JOURNALS

Tartof SY, Frankland TB, Slezak JM, Puzniak L, Ackerson BK, Jodar L, McLaughlin JM. Receipt of BNT162b2 Vaccine and COVID-19 Ambulatory Visits in US Children Younger Than 5 Years. *JAMA*. 2023 Sep 15. doi: 10.1001/jama.2023.17473.

Peterson J, Drazan D, Czajka H, Maguire J, Pregaldien JL, Seppa I, Maansson R, O'Neill R, Balmer P, Jodar L, Jansen KU, Anderson AS, Perez JL, Beeslaar J. Immunogenicity and safety of a pentavalent meningococcal ABCWY vaccine in adolescents and young adults: an observer-blind, active-controlled, randomised trial. *Lancet Infect Dis*. 2023 Aug 11:S1473-3099(23)00191-3. doi: 10.1016/S1473-3099(23)00191-3.

Tartof SY, Slezak JM, Puzniak L, Hong V, Frankland TB, Xie F, Ackerson BK, Valluri SR, Jodar L, McLaughlin JM. Effectiveness and durability of BNT162b2 vaccine against hospital and emergency department admissions due to SARS-CoV-2 omicron sub-lineages BA.1 and BA.2 in a large health system in the USA: a test-negative, case-control study. *Lancet Respir Med*. 2023 Feb;11(2):176-187. doi: 10.1016/S2213-2600(22)00354-X.

Peterson J, Drazan D, Czajka H, Maguire J, Pregaldien JL, Seppa I, Maansson R, O'Neill R, Balmer P, Jodar L, Jansen KU, Anderson AS, Perez JL, Beeslaar J. Immunogenicity and safety of a pentavalent meningococcal ABCWY vaccine in adolescents and young adults: an observer-blind, active-controlled, randomised trial. *Lancet Infect Dis*. 2023 Dec;23(12):1370-1382. doi: 10.1016/S1473-3099(23)00191-3.

Lewnard JA, Hong V, Bruxvoort KJ, Grant LR, Jódar L, Cané A, Arguedas A, Pomichowski ME, Gessner BD, Tartof SY. Burden of lower respiratory tract infections preventable by adult immunization with 15- and 20-valent pneumococcal conjugate vaccines in the United States. *Clin Infect Dis*. 2023 Jun 9:ciad355. doi: 10.1093/cid/ciad355.

Simon MW, Bataille R, Caldwell NS, Gessner BD, Jodar L, Lamberth E, Peng Y, Scott DA, Lei L, Giardina PC, Gruber WC, Jansen KU, Thompson A, Watson W. Safety and immunogenicity of a multivalent pneumococcal conjugate vaccine given with 13-valent pneumococcal conjugate vaccine in healthy infants: A phase 2 randomized trial. *Hum Vaccin Immunother*. 2023 Aug;19(2):2245727. doi: 10.1080/21645515.2023.2245727.

Rudolph AE, Khan FL, Shah A, Singh TG, Wiemken TL, Puzniak LA, Jodar L, McLaughlin JM. Effectiveness of BNT162b2 BA.4/5 bivalent mRNA vaccine against symptomatic COVID-19 among immunocompetent individuals testing at a large US retail pharmacy. *J Infect Dis*. 2023 Oct 31:jiad474. doi: 10.1093/infdis/jiad474.

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Tartof SY, Slezak JM, Puzniak L, Hong V, Frankland TB, Ackerson BK, Xie F, Takhar H, Ogun OA, Simmons S, Zamparo JM, Valluri SR, Jodar L, McLaughlin JM. Effectiveness of BNT162b2 BA.4/5 bivalent mRNA vaccine against a range of COVID-19 outcomes in a large health system in the USA: a test-negative case-control study. *Lancet Respir Med*. 2023 Dec;11(12):1089-1100. doi: 10.1016/S2213-2600(23)00306-5.

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Bruxvoort KJ, Fischer H, Lewnard JA, Hong VX, Pomichowski M, Grant LR, Jódar L, Gessner BD, Tartof SY. Risk of subsequent lower respiratory tract infection (LRTI) after hospitalization for COVID-19 LRTI and non-COVID-19 LRTI: a retrospective cohort study. *Pneumonia (Nathan)*. 2023 Oct 5;15(1):15. doi: 10.1186/s41479-023-00117-5.

Grant LR, Begier E, Theilacker C, Barry R, Hall-Murray C, Yan Q, Pope V, Pride MW, Jodar L, Gessner BD. Multicountry review of *Streptococcus pneumoniae* serotype distribution among adults with community-acquired pneumonia. *J Infect Dis*. 2023 Sep 4:jiad379. doi: 10.1093/infdis/jiad379.

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Williams RL, Hyams C, Robertshaw J, Gonzalez MG, Szasz-Benczur Z, White P, Maskell NA, Finn A, Barratt SL; AvonCAP Research Group. Use of illness severity scores to predict mortality in interstitial lung disease patients hospitalised with acute respiratory deterioration. *Respir Med.* 2023 Jun;212:107220. doi: 10.1016/j.rmed.2023.107220.

Grant LR, Slack MPE, Theilacker C, Vojicic J, Dion S, Reinert RR, Jodar L, Gessner BD. Distribution of serotypes causing invasive pneumococcal disease in older adults from high-income countries and impact of pediatric and adult vaccination policies. *Vaccine.* 2023 Aug 31;41(38):5662-5669. doi: 10.1016/j.vaccine.2023.08.001.

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Grant LR, Slack MPE, Theilacker C, Vojicic J, Dion S, Reinert RR, Jodar L, Gessner BD. Distribution of Serotypes Causing Invasive Pneumococcal Disease in Children From High-Income Countries and the Impact of Pediatric Pneumococcal Vaccination. *Clin Infect Dis.* 2023 Feb 8;76(3):e1062-e1070. doi: 10.1093/cid/ciac475.

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Lewnard JA, Bruxvoort KJ, Hong VX, Grant LR, Jódar L, Cané A, Gessner BD, Tartof SY. Effectiveness of Pneumococcal Conjugate Vaccination Against Virus-Associated Lower Respiratory Tract Infection Among Adults: A Case-Control Study. *J Infect Dis.* 2023 Feb 14;227(4):498-511. doi: 10.1093/infdis/jiac098.

Zavadskas D, Freimane Z, Karelis G, Ermina I, Harper LR, Bender C, Zhang P, Angulo FJ, Erber W, Bormane A, Gutmane E, Litauniece ZA, Tihonovs J, Griskevica A, Madhava H, Jodar L. Effectiveness of tick-borne encephalitis vaccination in Latvia, 2018-2020: an observational study. *Clin Microbiol Infect.* 2023 Jul 6:S1198-743X(23)00309-9. doi: 10.1016/j.cmi.2023.06.028.

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Wiemken TL, Khan F, Puzniak L, Yang W, Simmering J, Polgreen P, Nguyen JL, Jodar L, McLaughlin JM. Seasonal trends in COVID-19 cases, hospitalizations, and mortality in the United States and Europe. *Sci Rep.* 2023 Mar 8;13(1):3886. doi: 10.1038/s41598-023-31057-1.

Wiemken TL, McGrath LJ, Andersen KM, Khan F, Malhotra D, Alfred T, Nguyen JL, Puzniak L, Thoburn E, Jodar L, McLaughlin JM. Coronavirus Disease 2019 Severity and Risk of Subsequent Cardiovascular Events. *Clin Infect Dis.* 2023 Feb 8;76(3):e42-e50. doi:

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Lewnard JA, McLaughlin JM, Malden D, Hong V, Puzniak L, Ackerson BK, Lewin BJ, Kim JS, Shaw SF, Takhar H, Jodar L, Tartof SY. Effectiveness of nirmatrelvir-ritonavir in preventing hospital admissions and deaths in people with COVID-19: a cohort study in a large US health-care system. *Lancet Infect Dis*. 2023 Jul;23(7):806-815. doi: 10.1016/S1473-3099(23)00118-4. Epub 2023 Mar 15..

Stark JH, Pilz A, Jodar L, Moisi JC. The Epidemiology of Lyme Borreliosis in Europe: An Updated Review on a Growing Public Health Issue. *Vector Borne Zoonotic Dis*. 2023 Apr;23(4):139-141. doi: 10.1089/vbz.2022.0068. Epub 2023 Jan 27.

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Tartof SY, Slezak JM, Puzniak L, Hong V, Xie F, Ackerson BK, Valluri SR, Jodar L, McLaughlin JM. Durability of BNT162b2 vaccine against hospital and emergency department admissions due to the omicron and delta variants in a large health system in the USA: a test-negative case-control study. *Lancet Respir Med*. 2022 Jul;10(7):689-699. doi: 10.1016/S2213-2600(22)00101-1. Epub 2022 Apr 22

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