

October/November 2022 Report

Pfizer and BioNTech Report New Data on Omicron BA.4/BA.5-Adapted Bivalent Booster Demonstrating Improved Immune Response Against Emerging Omicron Sublineages - November 18, 2022

<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-report-new-data-omicron-ba4ba5-adapted>

- According to an analysis that examined the immune response induced by the Pfizer and BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine against new Omicron sublineages, the bivalent vaccine elicits a greater increase in neutralizing antibody tiers than the companies' original COVID-19 vaccine
- The Omicron BA.4/BA.5-adapted bivalent booster may help to provide improved protection against COVID-19 due to Omicron BA.4 and BA.5 sublineages as well as new sublineages that continue to increase in prevalence
- Neutralization data were generated using a nonvalidated fluorescent focus reduction neutralization test (FFRNT) one month after administration of a 30- μ g booster (fourth) dose of the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine or the original COVID-19 vaccine in adults aged 55 and older
- Results showed the bivalent vaccine booster elicited a greater rise in neutralizing antibody titers for all tested Omicron sublineages compared to the original vaccine, regardless of prior SARS-CoV-2 infection status.
 - Following a booster dose of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, neutralizing antibodies against BA.4.6 increased 11.1-fold (95% CI: 7.1, 17.3), while neutralizing antibodies against BA.2.75.2, BQ.1.1, and XBB.1 increased by 6.7-fold (95% CI: 4.4, 10.2), 8.7-fold (95% CI: 5.7, 13.3), and 4.8-fold (95% CI: 3.3, 6.9), respectively
 - By comparison, the neutralizing antibody titers against BA.4.6, BA.2.75.2, BQ.1.1, and XBB.1 following a booster dose of the companies' original COVID-19 vaccine increased 2.3-fold (95% CI: 1.9, 2.8), 2.1-fold (95% CI: 1.7, 2.5), 1.8-fold, (95% CI: 1.6, 2.2), and 1.5-fold (95% CI: 1.3, 1.8), respectively
- A booster dose of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine has been authorized for emergency use by the U.S. Food and Drug Administration (FDA) for ages 5 years and older
- It has also been granted marketing authorization in the EU by the European Commission for ages 5 years and older

Real-world study shows the effectiveness of the BA.4/5- adapted bivalent booster - November 22, 2022

<https://www.cnn.com/2022/11/22/health/vaccine-effectiveness-bivalent-boosters-cdc/index.html>

- The uptake of the bivalent boosters, which protect against the BA.4/5 sub variants as well as the original virus strain has been remarkably slow



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- Only 11% of eligible Americans have gotten them since becoming available in early September
- A new study found that the updated boosters protects against symptomatic infection in the range of 40% to 60%.
 - This is about the same range as typical efficacy for flu vaccines
 - This also means that the COVID-19 vaccines are no longer more than 90% protective against symptomatic infections as we saw during pre-Delta times
 - With delta, the efficacy dropped to the 70% range and then with Omicron, it dropped to the 50% range
- The study was led by CDC scientists and relied on health records from more than 360,000 tests given at nearly 10,000 retail pharmacies between September 14 and November 11
 - The study included people ages 18 and up who had COVID-19 symptoms and were not immunocompromised
- Compared with those who were unvaccinated, adults 18 to 49 who had gotten bivalent boosters were 43% less likely to get sick with a COVID-19 infection
- Those ages 50 to 64 were 28% less likely and those ages 65 and up were 22% less likely to get sick than the unvaccinated group
- If a person was two to three months past their last vaccine dose, the bivalent boosters added an average of 30% protection for those who were ages 18 to 49, 31% more protection if they were 50 to 64, and 28% more protection if they were 65 or older
- Those ages 18 to 49 who were eight months or more past their last dose of a vaccine had 56% added protection against a Covid-19 infection with symptoms; adults 50 to 64 had 48% added protection, and adults over 65 had 43% added protection, on top of whatever was left from previous vaccinations
- However by eight months, there is likely little protection left from previous shots against Omicron and its variants
- The added protection from the booster is expected to decline as the more resistant variants spread

Healthtech's success during the pandemic - October 18, 2022

<https://www.forbes.com/sites/garydrenik/2022/10/18/healthtechs-remarkable-success-during-the-pandemic-is-on-the-line/?sh=1d41ac6877ef>

- For certain demographics, the telehealth trend has not slowed down and experts say that we should not expect it to
- With IoT devices and wearables are developed, these remote consultations are expected to be able to pair with hardware that can monitor blood pressure, heart rate, blood glucose levels for checkup procedures, becoming even more widely adopted
- Back in 202 investors were eager to make heavy investments into life sciences because everything was shut down and the only way to get things back to normal was to fight the virus using technology that life sciences companies are good at developing
- Now that the immediate danger is over, things have cooled as some investors who were eager to make big bets on healthcare are diversifying those investments



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- However, there remains large interest in the medtech industry - especially health data

2022 Medtech trends

<https://www.medicaldevice-network.com/features/2022-medtech-the-shadow-of-covid-19-lingers-over-industry/>

- Digital health exploded during the global pandemic
 - The urgency of the pandemic acted as a catalyst to invest time and resources into innovation in preventative care
- Many publicly traded companies, which were recently valued in the billions, are now trading for cents on the dollar due to overpromising and underdelivering
- Massive government investments and new regulation initiatives made 2021 a record-breaking year for digital health
- 2022 saw a precipitous drop in funding and valuations
- Blaming the economic downturn is not a sufficient explanation as the digital health suffered more than other tech sectors
- An honest conversation about what innovation can and cannot achieve is invaluable
- The pandemic also brought about a notable increase in the number of collaborations and acquisitions between the medtech industry leaders and other health tech and tech companies
 - Johnson & Johnson joined with Microsoft to help build a cloud-connected software ecosystem around its digital surgery effort
 - Medtronic's Aoritic signed a collaboration with Cedar Medical for its cloud and AI based image-guided surgical solution
- The industry also saw larger tech companies make strategic acquisitions of AI platform companies like Microsoft's acquisition of Nuance, which already have the infrastructure that can be easily integrated into the company
- Medtech companies are progressing longer term digital and AI strategic plans, with the goal of improving device performance, personalizing medicine, and making their devices smarter
- Overall, the industry is embracing technology that connects people and allows them to collaborate more easily to provide optimal care
 - Ex. Cloud technology
- An increased use of data analytics and healthcare IT is expected to a larger emphasis on home healthcare, particularly remote monitoring of discharged patients to reduce hospital readmission rates
- Globally, medical device spend varied in 2022, with all geographic regions spending less compared to 2021
 - The largest decrease occurred in the Asia-Pacific region with the spend for COVID-19 related devices also decreasing dramatically
- Normal growth rates are predicted to continue in all regions from 2023 onwards
- The Ukraine-Russia conflict also influenced 2022 revenue trends due to worsening economic conditions



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- Beyond 2022, product development is expected to move towards cancer indications to address the pent-up demand for treatment, particularly delayed diagnoses, and interventions
- Looking beyond 2022, GlobalData's Pipelines Product Database starts indicating a medical device landscape where cancer is taking an increasingly prominent role

Nuance Healthcare

<https://www.nuance.com/index.html>

- Nuance is a market leader in creating clinical solutions that drive smart, efficient decision across healthcare and they are a pioneer in conversational AI and ambient intelligence
- Nuance designs innovative solutions that amplify human intelligence and revolutionize how people interact with technology in various industries - including healthcare, financial services, telecommunications, retails etc.
- Microsoft and Nuance have joined forces
- This will allow them to combine Nuance's best-in-class conversational AI and ambient intelligence and Microsoft's cloud infrastructure to build to create assistive technologies that seamlessly integrate into the way people work, connect with one another and engage with the digital world around them
- It has been almost two years since Nuance and Microsoft announced the integration of the Dragon Ambient eXperience (Nuance DAX) and Microsoft Teams
- Innovated by Nuance and Microsoft, the integration of Nuance DAX and Microsoft Teams for telehealth is part of the ongoing strategic partnership to accelerate the adoption of ambient clinical intelligence solutions to improve healthcare experiences by reducing administrative workloads that lead to clinician burnout

Dragon Ambient eXperience (DAX)

- DAX is a comprehensive, AI-powered, voice-enabled, ambient clinical intelligence solution
- It automatically documents patient encounters accurately and efficiently at the point of care
 - A dedicated mobile app securely captures the conversation at the point of care - this allows providers to connect with patients without having to use explicit voice commands
 - DAX also converts these conversations in comprehensive clinical notes tailored to each specialty that adhere to documentation standards, reducing the burden of compliance expertise, and enabling appropriate coding
 - This clinical solution integrates subject matter expertise and clinical knowledge with real-world experience to produce high-value adaptable, cross-specialty documentation
 - These AI generated notes go through a quality review process before being delivered to the clinical for signature in the EHR
 - DAX's AI learned the patterns of each provider over time creating an AI learning loop for continuous improvement



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- This information is integrated with electronic healthcare record systems

Johnson & Johnson collaborates with Microsoft

- Back in January of 2022, Johnson & Johnson announced their collaboration with Microsoft to help them build a cloud-connected software ecosystem around its digital surgery efforts
- Microsoft will serve as J&J's preferred cloud provider to link up its myriad connected medical devices and services
- This includes exercise apps designed to prepare a patient for surgery, planning and navigation software, and the robotically controlled hardware carrying out the procedure, as well as rehabilitation programs for the days that follow
- This collaboration will also help set the digital stage for J&J's upcoming Ottawa general surgery robot, which was previously slated for a clinical unveiling in the second half of 2022
- During the company's third-quarter earning call in November 2021, J&J Chief Financial Office said that Ottawa's first in-human procedures would be pushed back at least 2 years, following technical challenges and disruptions due to the COVID-19 pandemic

The future of Digital Surgery

<https://www.jnjmedtech.com/en-US/velys>

<https://www.jnjmedtech.com/en-US/company/depuy-synthes/news/depuy-synthes-acquires-cuptimize-hip-spine-analysis-providing-technology-help>

- Johnson & Johnson is partnering closely with hospitals, health systems, and leading technology companies to build a smart, connected, digital ecosystem that aims to improve efficiencies, advance insights, and promote collaboration
- They believe the transformative promise of digital surgery lies in capturing the learnings surgeons have gained from performing countless procedures and transferring that knowledge through data analytics and insights into technologies
- Those technologies can be leveraged across the continuum of care for more informed decision making and better connectivity with the patient pre- and post-operatively
- In orthopaedics Johnson & Johnson is taking bold steps to bring disruptive innovations to the market through a connected and personalized digital platform
 - Those innovations inform every step before, during, and after surgery through technologies that connect care teams with their patients by using action plans, education, direct feedback, and a companion mobile app
- This is the case for VELYS™ Digital Surgery, DePuy Synthes, the orthopaedics company of Johnson & Johnson
 - VELYS is a platform of connected technologies powered by data insights before, during, and after surgery, and designed to elevate the orthopaedic experience for patients, surgeons, and care teams



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- VELYS Digital Surgery solutions help enable greater insights for real-time decision-making, increased precision and consistency, and a more personalized care experience, with the goal of enhancing efficiencies and improving patient outcomes.
- In March 2022, DePuy Synthes acquired CUTIMIZE Hip-Spine Analysis, providing technology to help surgeons better understand, measure and address pelvic tilt
- CUPTIMIZE Hip-Spine Analysis is a digital screening tool that analyzes x-rays of the patient when standing and sitting to identify abnormal motion between a patient's spine and pelvis
- This gives surgeons an easy-to-use tool to better understand and address the impact of abnormal motion between the spine and pelvis in some patients who require total hip arthroplasty
- CUPTIMIZE Hip-Spine Analysis (CUPTIMIZE Analysis) enhances the surgical planning capabilities of VELYS™ Hip Navigation, one of the solutions within DePuy Synthes' VELYS Digital Surgery platform of connected technologies.
- Over time, J&J plans to integrate new technologies into the platform such as sensors, apps and patient selection tools, spanning orthopedic care from preop planning to postop rehabilitation.

Johnson and Johnson acquires Auris Health

<https://www.fiercebiotech.com/medtech/j-j-picks-up-robotic-surgery-maven-auris-health-and-founder-fred-moll-himself-3-4-billion>

- Johnson and Johnson acquired Auris Health in 2019 for \$5.8 billion
- Acquiring Auris Health, the designer of endoscopic hardware aimed at lung cancer, allowed J&J to dive deeper into robotic surgery
- This all-cash offer was made through J&J's Ethicon division
- Through this acquisition, J&J is aiming to simplify surgery, drive efficiency, reduce complications and improve outcomes for patients, making surgery safer

<https://www.jnjmedtech.com/en-US/product-family/monarch>

- MONARCH by Ethicon aims to create new treatment paradigms that help improve patient's lives as the first flexible robotic platform learned for use in bronchoscopy and urology procedures
- Through advanced robotics and micro instrumentation, they are committed to delivering innovative endoscopic possibilities
- Ethicon and Auris Health published additional results from the Monarch lung bronchoscopy robot gathered from their first study with live human participants
- The Monarch system uses an articulated tube to navigate the passages through the airway and the lungs to reach nodules suspected of harboring lung cancer
- Guided using a video game controller, it delivers a biopsy needle and retrieves samples for analysis
- The **latest publication**—featured in the college's official journal CHEST—included an exploratory analysis placing the study's overall diagnostic yield at 74.1%



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- In addition, a yield of 70% was achieved in lung nodules located outside of the patient's airway, compared to reported yields of 30% to 40% when using non-robotic technology
- Johnson and Johnson also acquired Orthotaxy in 2018 to help develop a comprehensive robotic-assisted orthopaedic surgery platform