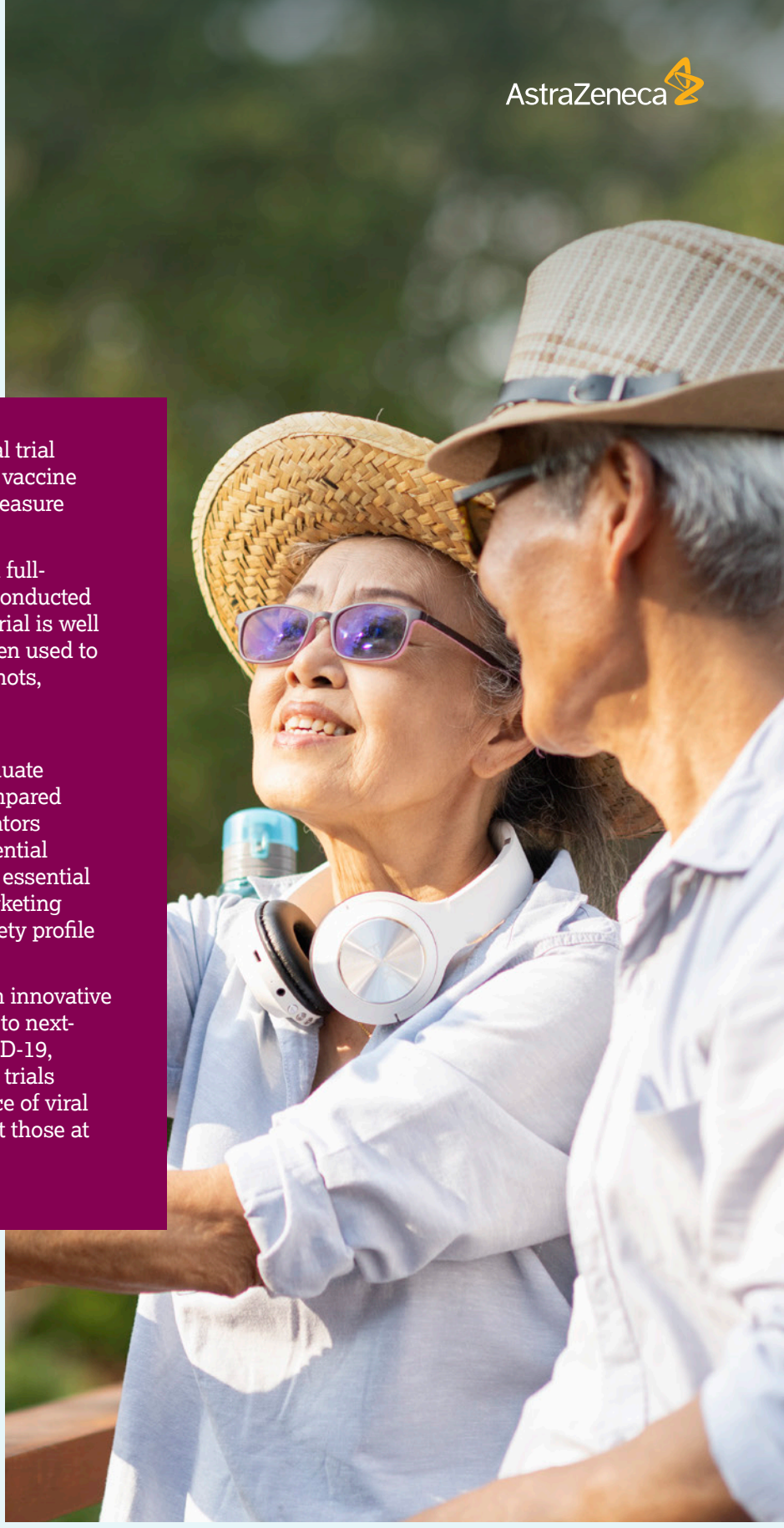
Annual Report 2023 Case Study

Working to bring medicines to patients faster



Immunobridging is an approach to a clinical trial used to infer effectiveness of a new drug or vaccine candidate through an accepted surrogate measure for efficacy.

Immunobridging trials are often used when full-scale efficacy trials may not be feasible or conducted under a fast enough timeline. This type of trial is well established for testing vaccines and has been used to develop and authorise COVID-19 booster shots, yearly influenza vaccine updates, HPV and pneumococcal vaccines.[1–4]

Immunobridging trials are also used to evaluate tolerability of the candidate therapeutic compared to the control. Health authorities and regulators agree that demonstrating tolerability of potential new products based on immunobridging is essential as well as the value in conducting post-marketing authorisation studies to further support safety profile and effectiveness.[5,6]

AstraZeneca is helping to lead the way with innovative immunobridging trials to accelerate access to next-generation monoclonal antibodies for COVID-19, where alternatives to running large efficacy trials are especially important given the rapid pace of viral evolution and the need to potentially protect those at highest risk for severe disease.

For more information, scan the QR code or click here.

Source of content: 2023 AstraZeneca Annual Report and www.astrazeneca.com.

1. Diaco M et al. Introductory Paper: High-Dose Influenza Vaccine. Vaccine. 2021;39:A1-A5.
2. Fink D. Immunobridging to Evaluate Vaccines. https://cdn.who.int/media/docs/default-source/blue-print/doran-fink_4_immunobridging_vrconsultation_6.12.2021.pdf. [Last accessed: April 2023]
3. PREVNAR 20 Package Insert. https://labeling.pfizer.com/ShowLabeling.aspx?id=15428 http://vaers.hhs.gov/. [Last accessed: April 2023]
4. Donken R et al. Immunogenicity of 2 and 3 Doses of the Quadrivalent Human Papillomavirus Vaccine up to 120 Months Postvaccination: Follow-up of a Randomized Clinical Trial. Clinical Infectious Diseases. 2020;71(4):1022-1029.
5. Medicines & Healthcare products Regulatory Agency Access Consortium: Alignment with ICMRA Consensus on Immunobridging for Authorising New COVID-19 Vaccines - GOV.UK. https://www.gov.uk/government/publications/access-consortium-alignment-with-icmra-consensus-on-immunobridging-for-authorising-new-covid-19-vaccines/access-consortium-alignment-with-icmra-consensus-on-immunobridging-for-authorising-new-covid-19-vaccines. [Last accessed: April 2023]
6. European Medicines Agency Joint EMA-FDA Workshop: Efficacy of Monoclonal Antibodies in the Context of Rapidly Evolving SARS-CoV-2 Variants. https://www.ema.europa.eu/en/events/joint-ema-fda-workshop-efficacy-monoclonal-antibodies-context-rapidly-evolving-sars-cov-2-variants. [Last accessed: April 2023]