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Vaccine Efficacy waning estimation and extrapolation using causal inference

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Jyoti is a Statistical Leader at GSK Vaccine (Belgium). She has worked across different indications and phases for Viral vaccine and is also working on Neuroscience study. Her current research interest are adaptive clinical study design, correlate of protection and more recently neuroscience specific statistical methodology.

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Andrea Callegaro is Director, Biostatistics at GSK Vaccines (Belgium). He is a biostatistician with about 20 years' experience. Since 2013 he is working in a team of statistical solutions and innovation. Topics of active research: clinical trials, adaptive biomarker designs, surrogate endpoints (correlate of protection), causal inference.

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Understanding how vaccine efficacy (VE) decays over time is relevant for policy making, especially regarding vaccination strategies. We consider a hypothetical setting, where placebo subjects are allowed to take vaccination at the end of the PIII trial to let the placebo's participants take the advantage of vaccination, while vaccinated subjects are followed for additional years to estimate the persistence of the efficacy.

We have explored methodology to estimate the VE decay using causal inference along with parametric survival models. A flexible parametric survival models adjusting for confounding factors has been fit and then G-computation has been used to adjust for covariates and predict/extrapolate the vaccine efficacy using two different estimand – one measuring the VE measuring the cumulative effect from time 0 to t (cumulative incidence ratio) and another measuring the effect at time t (hazard ratio).

Use of parametric survival models together with G-computation is an efficient way to predict and extrapolate of vaccine efficacy in vaccine setting.