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"The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure"

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Title: Pragmatic RCTs and the power of vaccine probe analysis: The experience from Finland

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Finland has a unique position for large field vaccine trials with a history of over 70 years after participation in the polio Salk trial in the 1950ies, followed by large pragmatic meningococcus A, Haemophilus influenzae type b, pneumococcal, HPV and influenza vaccine trials.
Finland has developed multiple health care, social care and population registers since 1960ies. All registers are nationwide, linkable with each other, and affordable. Data collection in all registers is mandatory, electronic, automated, structured and, in most cases, real-time. Due to the national health insurance coverage of all permanent residents and accessible public healthcare, the registers capture the healthcare events without selection bias. Additionally, the the data collection can be augmented by using biobanks and nationwide patient-file data using The Patient Data Repository of the Kanta Services.
Large post-licensure vaccine trials are powerful tools, especially when the best possible study design, a randomized controlled blinded trial is meticulously conducted. This will allow the use of vaccine probe design to estimate the disease burden (vaccine-preventable disease incidence, VPDI) for outcomes of unknown etiological fraction by comparing the incidence in vaccinated and unvaccinated trial arms. A pragmatic trial of a pneumococcal conjugate vaccination in infants will be presented to demonstrate the low yield of the conventional definition of invasive pneumococcal disease (IPD) due to poor detection of septic syndromes by blood culture.
Using vaccine probe design, sensitive detection will result in proper estimation of the disease burden and will promote the introduction of vaccination programs to gain public health benefits.