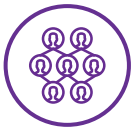
COVID-19 Post-Approval Safety Studies

Evidera can design, manage, and execute your global strategy

Evidera | PPD

Understanding the real-world safety of COVID-19 vaccines and treatments is an important research need for product sponsors. Evidera's leading experience with COVID-19 products, and with development and implementation of post-authorization safety studies (PASS) and regulated and non-regulated post-marketing studies (PMS), means we are well positioned to partner with you to effectively plan and execute your post-authorization safety strategy.



Differentiated, multi-faceted recruitment and retention strategies

Unique study design strategies and experience with a variety of secondary data sources

State-of-the-art technology platform for real-world data (RWD) collection

Your Challenges	Evidera's Solutions
Meeting the pressure for real-time signal detection requested by health authorities	• Burden-free, patient-centric data collection via dedicated app, medical confirmation of safety data • Design of safety metrics and generation of automated reports • Identification of trends via specialized data analytics platform
COVID-19 vaccination data sources are challenging (vaccination data often not linked to EMRs)	• Bespoke prospective data collection to maximize availability and quality of exposure and safety outcomes data and allowing for real-time signal detection • Decentralized, direct-to-patient and patient-centered study designs
Diverse and evolving vaccination settings create recruitment and data collection challenges	• Tailored, site-support solutions, including on-site staff to reduce site burden, and optimize recruitment, consent, and data collection • Streamlined, fit-for-purpose electronic RWD collection platform
Evolving and varied regulatory authority guidelines	• Experienced staff with regulatory insights who can anticipate and proactively assess and recommend a post-marketing safety strategy • Customized solutions to address research questions in the most rigorous and cost-effective way, without being tied to specific data sources or study designs
Urgency to collect post-authorizaton data quickly	• Expedited start-up timelines, leveraging our COVID-19 study experience and established processes • Streamlined study designs and protocol templates
Unprecedented research questions in a changing landscape	• Collaborative approach of our experienced epidemiologists and operations specialists with our clients to generate tailored study designs to meet new study objectives • Regulatory-grade, feasible solutions blending scientific rigor and operational excellence

40+
PASS/PMS studies completed

100+
database projects completed

70+
safety studies and programs in the past five years

20+
years of experience in post-approval safety studies

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