REAL WORLD EVIDENCE AND LATE PHASE

REAL WORLD EVIDENCE AND HEALTH ECONOMICS

The aim of real world evidence (RWE) gathering is to tell the "value story" of a Sponsor's product. Beyond gaining market approval, this can include increasing reimbursement in an exceedingly competitive marketplace, expanding market penetration, and maximizing potential return on investment.

Real world research can include:

- Phase IV trials
- Pragmatic trials
- Registries
- Post-authorization safety/efficacy studies
- Expanded access/compassionate use programs
- Observational epidemiologic studies
- Health economics studies

MEDPACE EXPERTS, EXPERIENCE AND EXECUTION IN HEALTH ECONOMICS

Medpace has conducted hundreds of interventional and observational late phase studies involving thousands of patients and sites globally. A core team of late phase research experts is supported by medical, regulatory and operational experts with in-depth knowledge and experience. Medpace's medical experts are deeply involved in studies in the early stages of development, ensuring that they can be designed with economic considerations in mind and provide credible data to support product approval and reimbursement.

Medpace can help Sponsors establish which health economic approaches are best for their product development. Relevant capabilities include:

- Cost-minimization
- Cost-effectiveness analysis
- Cost-utility analysis
- Cost-benefit analysis
- Budget impact modeling

REAL WORLD EVIDENCE AND HEALTH ECONOMICS

Drawing upon our extensive experience, we can help Sponsors determine the best timing for initiating economic analyses, whether it be earlier or later in the drug development cycle. Medpace has the capability to conduct standalone or piggyback economic analyses. We have utilized various sources of claims data and electronic medical records (EMR), including Centers for United States (US) Medicare/Medicaid Services, US Veterans Affairs, INTERMACS, and several payer claims and hospital billing databases.

"CLOSING THE LOOP" ON VALUE

With the cost of drug development now estimated at US$2.6 billion by the Tufts Center for the Study of Drug Development (CSDD), an understanding of the economics of a Sponsor's product is essential to maximizing the return on investment. As a full-service partner, Medpace engages with Sponsors from early development through approval and post-marketing safety requirements. Real world research brings this development cycle full circle, providing an accountable, seamless, integrated, and efficient approach to drug and medical device development.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.