MEDPACE

REAL WORLD EVIDENCE AND LATE PHASE

PLANNING FOR AND CONDUCTING RWE AND LATE PHASE CLINICAL RESEARCH

Medpace, long known for its therapeutic and regulatory capabilities, is well-resourced to assist with your post-approval strategies and to conduct Phase IIIb-IV studies in both pharmaceutical and medical device areas. Medpace integrates our strong therapeutic leadership with an in-depth understanding of the challenges and proper conduct of post-marketing research. Our global operational reach and full-service capabilities for Phase I-IV studies can help you achieve your scientific and commercial objectives.

HOW OUR EPIDEMIOLOGY AND LATE PHASE RESEARCH TEAM CAN HELP:

- Develop integrated post-approval strategies with your early-stage clinical development plans
- Medical, regulatory, clinical, and late phase experts are deeply embedded in your studies to provide strategic and operational leadership
- A breadth of resources to conduct global research yet an agile culture that enables swift adaptability as study requirements shift
- Targeted Site Selection reflecting real world drug and medical device use
- Dedicated submissions team to accelerate startup
- Global and localized regulatory leadership from early phase through late phase
- Expertise, resources and infrastructure to transition from randomized controlled trial process to real world evidence generation

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Therapeutic, regulatory and safety experts collaborate throughout study design and execution
- Epidemiology and late phase research teams with over 100 years of combined clinical research experience, including 50 years dedicated exclusively to RWE and post-market research

EXPERIENCE

- Conducted over 140 late phase studies involving 40,000 patients at 2000 investigator sites globally
- Pharmaceutical and medical device clinical trials and observational studies
- Key therapeutic areas including cardiology, metabolic, infectious disease, and oncology, as well as extensive experience in pediatrics
- Experience in over 45 countries

EXECUTION

- Post-approval strategies incorporated into earlier phase study design
- Streamlined global operations with an integrated approach to Risk-Based Monitoring (RBM) throughout the entire project lifecycle.
- Comprehensive suite of services to support all facets of pre- and post-approval clinical research

MAKING THE COMPLEX SEAMLESS EXPERIENCE FROM BEGINNING TO END

Medpace has been supporting its clients for 30 years throughout the drug and device development life cycle. Our epidemiology, medical, and operational experts have accrued solid experience in study design, protocol development, and scientific oversight of Real-World and Late Phase research studies. Medpace has managed more than 140 interventional and observational studies involving over 40,000 patients at more than 2,000 global sites. With vast experience in global cardiology, metabolic, infectious disease, and oncology clinical trials as well as a specialty in pediatrics, Medpace has the therapeutic, regulatory, and safety experts to design drug and device studies efficiently in the early stages with late phase in mind.

FULL RANGE OF STUDY SUPPORT

Medpace conducts both interventional and noninterventional type studies:

- Phase IIIb and IV randomized clinical trials
- Observational epidemiologic studies
- Expanded Access Programs
- Post-authorization safety and efficacy studies
- Health Economics and Outcomes Research
- Competitive marketing claims studies
- Registries

KEY RELATIONSHIPS

Medpace's epidemiology and late phase research team engages with The European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Being a partner center of the ENCePP, Medpace is able to register appropriate studies we conduct on the ENCePP e-register, a publicly accessible resource for the registration of pharmacoepidemiologic and pharmacovigilance studies, which also serves as an EU PAS Register for Post-Authorization Safety Studies (PASS).

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.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.