MEDPACE

RWE AND LATE PHASE

Experts. Experience. Execution.

Discover the POWER OF X®

The Power of X in RWE and Late Phase

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 100 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

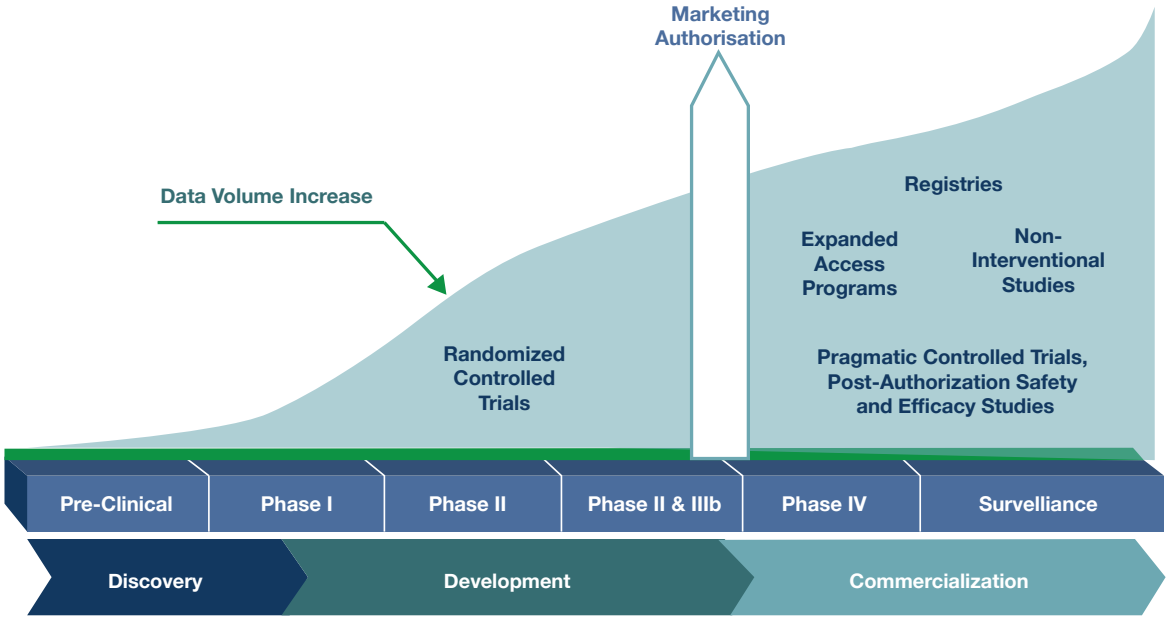
Planning for and Conducting RWE and Late Phase Clinical Research

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. Our global operational reach and full-service capabilities for Phase I-IV studies can help you achieve your scientific and commercial objectives.

Comprehensive Services

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



Experience from beginning to end

Medpace has been supporting its clients for over 20 years throughout the drug and device development life cycle. We have conducted over 100 late phase studies involving 40,000 patients at 2000 investigator sites globally. 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 non-interventional 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 Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Being a partner centre 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 pharmacoepidemiological and pharmacovigilance studies, which also serves as an EU PAS Register for Post-Authorization Safety Studies (PASS).

Who We Are

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug and device development services.

MEDPACE

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