



**Jason Monteleone**  
Chief Executive Officer  
JMonteleone@clinipace.com

**CLINIPACE WORLDWIDE**

Helfmann-Park 10  
65760 Eschborn, Germany

Tel. +49 6196 7709-0  
Fax +49 6196 7709-120

www.clinipace.com

BVMA member since 2004  
Audits passed in 2004, 2006,  
2009, 2012, 2015 and 2018



**HISTORY AND MISSION**

Clinipace Worldwide, a global CRO serves the unique needs of venture-backed, mid-tier and strategic pharmaceutical, biotechnology and medical device firms, helping them advance drug candidates to deliver successful stakeholder and patient outcomes. We leverage extensive therapeutic experience, clinical trial expertise, and our proprietary eClinical platform TEMPO™ to support our customers in achieving some of their most important goals: Executing regulatory strategies, optimizing clinical development timelines and completing high quality trials.

**HIGHLIGHTS**

Clinipace Worldwide is a global contract research organization where clinical expertise is the backbone and technology is the catalyst to your success. We leverage our clinical and scientific expertise with proprietary technology to optimize and execute your drug development program. From managing your entire clinical drug development program to conducting an individual trial, our experts bring extensive operational, regulatory and therapeutic experience in building a well-defined strategy and plan. Whether you need support for a single service or a full suite of services, we've got you covered. Clinipace has completed more than 1,500 clinical trials and 1,500 regulatory and statistical consulting projects and operates in North America, South American, Europe, and Asia.

**SERVICES**

**Clinical Development**

- ▷ Biostatistics
- ▷ Clinical Monitoring & Data Management
- ▷ GCP training
- ▷ Global Study Feasibility
- ▷ GxP/CMC Quality Assurance Consultancy
- ▷ Legal Representation
- ▷ Medical Affairs & Monitoring
- ▷ Patient Recruitment
- ▷ Pharmacovigilance & Safety Surveillance
- ▷ Project Management
- ▷ Regulatory & Strategic Consultancy
- ▷ Regulatory Submissions & Filings
- ▷ Site Selection & Management
- ▷ TEMPO eClinical Platform

**Regulatory and Strategic Development:**

- ▷ Chemistry & Manufacturing
- ▷ Clinical Trial Applications & Product Registrations
- ▷ GxP Auditing & QA Consultancy
- ▷ Legal Representation
- ▷ Product Development Strategy
- ▷ Regulatory Affairs
- ▷ Writing & e-publishing

**Therapeutics Areas:**

- ▷ Oncology, Cardiology, Nephrology, Urology
- ▷ CNS, Diabetes, ENT, Eye & Respiratory
- ▷ Immunology, Infectious Disease
- ▷ Nutrition, Orthopaedic

