

■ COMPANY PROFILE



Jason Monteleone
Chief Executive Officer
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History and Mission

As leaders in research, we are entrusted with important work. So naturally, we think it is important to provide an environment where our employees know their ideas, opinions and contributions all matter. We value transparency and integrity and support a performance-oriented culture where everyone is encouraged to collaborate. We want our employees to know that working here is more than a just job – it's an opportunity to change lives and contribute to the future of medicine.

Highlights

At **Clinipace**, a global, full-service contract research organization (CRO), our approach to clinical research is personal. We deliver a level of collaboration and flexibility not possible in a traditional CRO environment. With personalized services and solutions, local regulatory expertise and therapeutic leadership, we overcome the most difficult industry challenges across all major therapeutic areas including oncology, gastroenterology, nephrology and urology, rare disease, and women's health. We strive to improve the way clinical research is performed and impact the future of health care using the most advanced technology and a CHALLENGE ACCEPTED approach.



- Your right-size CRO
- Your trusted global clinical development partner
- Your expert regulatory affairs consultant
- Your broad technology infrastructure provider
- Your experienced therapeutic area and medical expert team

CLINIPACE

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



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Services

Clinical Development Phase I-IV

- Biostatistics and statistical programming
- Clinical data management
- Clinical operations
- Clinical technology
- Investigator recruitment and site selection
- Medical monitoring
- Medical writing
- Project management
- Protocol feasibility
- Quality assurance
- Regulatory affairs
- Safety/pharmacovigilance

Regulatory Affairs

- Product development
- Portfolio management
- Regulatory affairs
- Manufacturing and quality support
- Medical and regulatory writing
- Regulatory publishing/submissions

Therapeutic Areas

- Gastroenterology, nephrology and urology, oncology, rare disease, and women's health
- Cardiology, CNS, ENT, immunology, infectious diseases and vaccines, nutrition, orthopaedic, and respiratory