StatisticaMedica A Catalyst forMedical Breakthroughs

When it comes to the world of medical research and development, three major aspects play a crucial role in its success: time to market, low costs, and the effectiveness of the end product. Where there is absolutely no room for error, the only way to ensure favorable outcomes is by knowing the answers to the toughest questions. And that's exactly what forms the basis of StatisticaMedica. A clinical research organization, StatisticaMedica specializes in the biostatistics and data management activities of clinical trials in the pharmaceutical, medical device, food, and healthcare industries. The company assists its clients in the design, analysis, and reporting of clinical studies, with the primary focus on accelerating the path from research questions to research findings. "We provide scientifically clear and methodologically robust answers that can drive the clinical decision-making process forward, using the strictest scientific standards and the highest level of regulatory compliance," explains Dr. Gloria Crispino, the founder and CEO of StatisticaMedica.


Dr. Gloria Crispino

StatisticaMedica sets the cornerstone for quality, clarity, and reliability through a combined knowledge of over 100 years on statistical issues in clinical trials and cutting-edge experience in the most pressing medical conditions, both in adult and pediatric research. In addition to accelerating the path to commercialization of medicinal products and medical devices, the company targets the key statistical and data integration issues throughout the full development plan to reduce the cost of clinical research and shorten the path to improved patient outcomes.

StatisticaMedica is focused on delivering value where it matters: cycle time and success rate. "We do this by helping clients not only target the data that matters the most, which reduces the time to study implementation and results delivery, but also provide a reliable, clear and statistically valid answer to anticipate the challenges of designing and implementing a study and addressing the regulatory concerns heads on," adds Gloria. She defines StatisticaMedica's role as 'a methodological bridge,' helping clients to move through the translational continuum of the clinical development plan with robust tools, cross over pitfalls and leap successfully from one phase to the next.

Furthermore, StatisticaMedica works at the interface between principal investigator-lead research and sponsor trials in adult as well as pediatric research. StatisticaMedica offers a boutique service focused on the overall development

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plan, bringing together their know-how in statistics, data management, and medical reporting to create a holistic, interconnected approach that accelerates the development path and increases the quality of the output. The company's small size allows them to adapt quickly to the requirements of each phase of the study, helping reduce time and waste and improving the chances of commercialization of new products. StatisticaMedica's team of experts solves the client's core statistical issues of clinical research - study design, sample size, treatment allocation, methods of analysis – to provide clear, reliable, compliant solutions. In addition, they offer the full spectrum of services from ad-hoc statistical consulting to a fully integrated service, allowing clients to deliver under the strictest regulatory requirements with certified data integration and standardization methods, for pharmaceutical products and medical devices. What makes StatisticaMedica stand out is its prowess in the translational space between clinicians, healthcare providers, and industry sponsors, in the US and European jurisdictions. "With this breath of exposure 'we see more' and can provide alternative solutions to the design, implementation, and analysis of studies that reduce costs and maximize value," explains Gloria.

Equipped for the future, StatisticaMedica currently maintains compliance for the upcoming MDR and IVDR regulations. "We are working with large companies as well as innovative SMEs since early 2018 to prepare technical files and design new trials that address the stringent requirements for clinical evidence under the new regulations," adds Gloria. Moreover, the company takes pride in having a list of more than 450 publications, several books, and book chapters, and its contribution to raising several million euros in grant awards for research in academia and industry. Ph