

Recognition of the work of a CRO: How is it achieved and why?

Find out what a contract research organisation can contribute during the clinical research process. Is its work recognised as often as it deserves, and how does it bring value to your journey?

Based in Spain, APICES is a full-service European contract research organisation (CRO) with international vocation and capabilities, and with more than 13 years of experience. APICES has in-depth knowledge of oncology, immunology, haematology and all other therapeutic areas. It provides a wide range of research and clinical development services, from project design to publication of results, to improve the quality of investigational product development through the optimisation of clinical trials during the development of processes and activities, and the inclusion of non-interventional clinical studies for market access.

The goal of APICES is to ensure that you are delighted with our services, providing maximum satisfaction on your clinical development journey. APICES is always striving to exceed client needs and will provide added value by understanding and addressing the main challenges faced by each client during their trials. We will do this through simplifying the clinical development process by implementing key solutions in successful study design, clinical development planning and regulatory timelines to meet our clients' milestones.

Team drives client satisfaction

Always focused on achieving the highest quality results in every project, we tailor our team and resources to the needs and requirements of any study in which we participate. Excellence for our clients and client satisfaction are our key drivers since 2009, proven with >40 public acknowledgements in scientific journals to date.

At APICES we have highly trained professionals, with more than 20 years of

experience in key positions, who have been part of our organisation since its beginnings and provide a real and up-to-date vision of the world of clinical research and new scientific developments.

We have formed a team of highly qualified, dynamic people specialising in different fields, with extensive experience in CROs and pharmaceuticals. Experts who understand clinical requirements, cultural and linguistic specificities, and regulatory requirements per country to implement the best option for a project based on strategic thinking in study design, clinical development planning and successful regulatory strategies.

Experience

Often, our clients need to outsource or find a partner who can develop and coordinate all the activities which are necessary to carry out clinical research and development. We efficiently and effectively facilitate, with the expertise of our resources, the development of clinical projects of any size and therapeutic area.

We provide a full range of services that includes project design, project management, start-up, monitoring, medical monitoring, pharmacovigilance, data management, biostatistics, medical writing and quality assurance, in phases I – IV of clinical trials,

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non-interventional studies and real-world evidence studies, with expert project management to prevent and anticipate any possible deviation from the original project objectives through contingency plans.

The success of these projects requires rapid site identification and study start-up, efficient patient recruitment and adherence to study timelines. Assessing project-specific risks allows us to tailor quality assurance resources to a risk-based approach, focused on client needs and project complexity, also aligning cost and service time with quality in order to meet client requirements. Our in-depth experience of the European regulatory process, and knowledge of sites and investigators, provides our clients with the ability to meet start-up milestones.

The process simplification for complex clinical projects that we provide is based on the application of a full range of field-proven technology tools and our experience and resources to manage trials of any size in the most efficient way.

Commitment to quality

APICES is proud to be the first CRO to have implemented an ISO 9001:2015 compliant Quality Management System, based on our 'Service Process Map', which includes the owner, inputs, resources, risks, controls and key performance indicators corresponding to each of the internal steps during the clinical research process.

We have developed the Quality Management System, with a comprehensive list of Standard Operating Procedures (SOPs) to cover the execution of the different services we offer. These procedures are designed to move hand in hand with the client throughout the project, verifying the results through internal quality controls in order to progress quickly and correctly to the next step.

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Our expert project planning and management will help to reduce project risk and minimise delays, thus decreasing cost and ensuring that agreed deadlines are met to the highest quality.

We are acutely aware of the increasing importance of our clients' ESG (environmental, social and governance) requirements and strive to be a leading service provider in this area.

Recognition

During this time, APICES staff have featured repeatedly in well-respected scientific journals in more than 40 acknowledgments, and even as authors in some cases. Their participation and contribution to the clinical trials has been recognised in high-impact publications, including *The Lancet Oncology*, *Annals of Hematology*, *Annals of Oncology*, *Journal of Clinical Oncology*, *International Archives of Allergy and Immunology*, *European Journal of Cancer*, *The Oncologist*, and *Clinical and Translational Oncology*, among others.

These continued acknowledgements in high-impact publications, mainly in the field of oncology and haematology, are not simply a coincidence. Our considerable expertise in running immuno-oncology and haematology trials is considered to be a positive aspect that reinforces this evidence.

This is also supported by the fact that, while managing these studies, APICES offers its clients added value, beyond the contracted service itself. Other aspects that may have a favourable influence on these acknowledgements are the team's deep involvement in the projects and the accessibility to top management, who are on hand to accompany the client until a satisfactory end product is obtained. From the beginning of the project right up to the publication of results, we establish fluid communication and work on building good relationships that allow unforeseen events to be dealt with smoothly, and in coordination with the sponsor.

As a result, APICES can be seen as a reliable partner founding its growth on confidence and client satisfaction, flexibility and partnership vocation, quality and experience in clinical research, as well as global resources. It ensures that its clients are delighted with the services, providing them with maximum satisfaction on their clinical development journey. ●