Know How, Who and Where. Operational Agility and Efficiency result in successful Phase I/IIa study performed in Europe

The Situation

A clinical stage biopharmaceutical American company, developing first in class and best in class patented molecules, initiated a bid for a phase I/IIa study as part of a global clinical development program for their novel anti-tumor agent to be trialed as 1st line treatment for a metastatic solid tumor. The main objective of this trial was to establish the maximum tolerated dose (MTD) in this type of patients. The recruitment goal for this phase I/IIa study was **25 patients**.

The Sponsor required a CRO with the following capabilities: strong experience in early phases, high knowledge of the therapeutic area and connections with the most important KOLs in the world of oncology and this specific type of tumor. On the other hand, meeting deadlines would be critical since it would greatly affect the future marketing strategy of the product.

Meeting the Sponsor's initial requirements, APICES was retained as CRO of choice for this Phase I/IIa Trial.

The Challenge

APICES presented an ambitious but realistic proposal, based on optimizing the deadlines to carry out the study and proposing the activation of sites exclusively in Spain in order to optimize the deadlines as well as the costs of the study.

Among others, the client selected APICES for the following key reasons:

- Fast approval times
- Highly experienced investigators and sites
- High number of patients available
- Population and patients willing to participate in oncology trials
- Reasonable costs and a public healthcare system that covers some medical tests allowing them to be included in the usual portfolio of services

Based on the prevalence of the disease, trial inclusion criteria and ambitious deadlines in terms of recruitment, it was decided to activate and recruit patients in **4 sites**.

The Actions

Among others, the key actions taken were:

Protocol Review: an in-depth review of the Protocol by our medical monitors, KOLs and medical writing team, incorporating ideas that contributed to improving the overall trial strategy.

Feasibility: a selection of high performing sites was made, combining data science, experience, and close relationship with the best investigators.

Regulatory & Start Up: APICES selected the fastest central Ethic Committee and was advancing the submission to the Competent Authority (AEMPS) while simultaneously managing all the start-up activities with the high performing sites involved.

Project Management and Monitoring: an ad hoc stable team of Project Managers and CRAs with experience in early phases in oncology and committed to the project was created in order to save time and resources for the sponsor.

Data Safety: APICES suggested the creation of a DSMB (Data and Safety Monitoring Board) with the aim of constantly evaluating the safety of the data and independently of our pharmacovigilance and medical monitoring department and the sponsor.

The Results

Operational agility and efficiency along with deep local industry knowledge of “Know How, Know Who and Know Where”, expert Oncology CRO, and strong relationships with sites, enabled APICES to quickly achieve the patient recruitment goal.

The sponsor was impressed with the capabilities of APICES and the sites being able to carry out this study in such an agile and smooth way.

APICES with the Spanish sites and the rest of the European countries, has become one of the sponsor's strategic providers for the implementation of the foreseeable next steps for the approval of this promising molecule.