Know How & Who, Operational Agility and Efficiency result in successful rescue of a Phase III Oncology study

The Situation

A multinational biopharmaceutical company initiated a global phase III clinical development program for their novel anti-tumor agent to be trialed as 2nd or 3rd line treatment for a metastatic solid tumor. A global CRO was engaged to manage sites across the US, Europe, and Asia Pacific with the objective to recruit 500 patients globally.

After a delayed site startup and too slow global patient recruitment, **APICES** was engaged by the sponsor to take over the clinical management of the study as the regional CRO for **28** proposed sites in France, Italy, Portugal, and Spain.

The Challenge

The initial study timelines needed to be kept, despite the change in CRO mid-way through the study's start up, requiring **APICES** to meet very rapid activation and start-up timelines.

The challenge was to accelerate a seamless transition with all the stakeholders, while liaising with the global CRO.

The Actions

The first action was to analyze the situation with the Sponsor, the investigators, and the sites. The following shortcomings were identified:

- Incorrect site selection due to unawareness of the specialized hospitals and their referral networks at a national level.

- Lack of follow-up of investigators when completing the feasibility study.

- Lack of relationship or impersonal approach with investigators.

- Lack of responsiveness and flexibility from the large Global CRO due to their excessive infrastructure and hierarchy resulting in lack of ownership while causing delays leading the Sponsor to feel underserved.

- Lack of experienced CRAs combined with high turnover rates.

In addition, the Sponsor's main objective was to use this study as an introduction and position itself with the investigators as a reference partner in all participating countries, a key objective that was not being met.

Based on the Sponsor's main objective and the shortcomings identified, the following action plan was implemented:

- A new selection of high performing sites was made, thus adding sites of great value, that had not been initially considered.

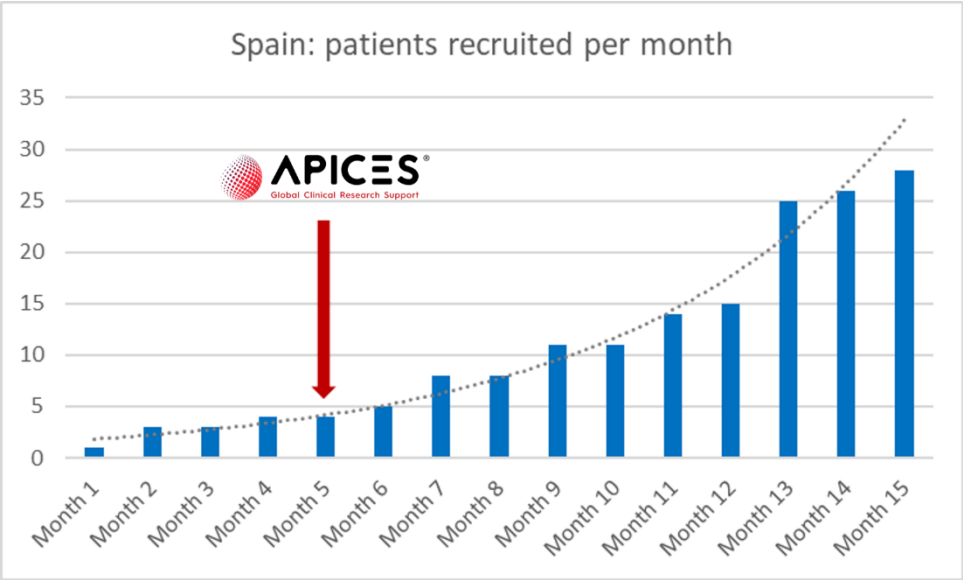
- Recruitment in previously opened sites was promoted through personal visits to motivate investigators and resolve any type of barriers that may have arisen.

- The start-up and monitoring were carried out by the in-house clinical operations team from APICES headquarters in Spain, resulting in greater control of the project, improved recruitment rates, as well as a better overall cost control.

The Results

Operational agility and efficiency along with deep local industry knowledge of "Know How and Know Who", expert Oncology CRO, and strong relationships with sites, enabled APICES to quickly improve patient recruitment.

Despite starting well behind the rest of the countries, **Spain** became the 3rd highest recruiting country globally – accounting for almost **10 % of the patients** to date.



Less than 1 patient per month during the first 5 months, then an average of 3 patients per month with APICES.

The Sponsor was impressed with APICES' contribution and has also praised the valuable contribution by the highly dedicated APICES team in Spain - which has helped to get his project back on track and meet the critical clinical development milestones.