Case Study:

OPTIMIZING GLOBAL IMMUNO-ONCOLOGY TRIALS: SUCCESS IN PHASE III RENAL CELL CARCINOMA STUDY EXECUTION

GLOBAL PHASE III IMMUNO-ONCOLOGY STUDY FOR RENAL CELL CARCINOMA

855 PATIENTS

180 SITES

26 COUNTRIES

SERVICES PROVIDED

- Clinical Operations
- Feasibility
- Regulatory Submissions
- Start-up Services

CHALLENGES

- Study timelines required quick identification and selection of sites globally.
- Use of immunologic backbone on study required vigilance in responding to early signs of Immune Related Adverse Events (irAEs) to prevent higher grade events. Increased level of monitoring and vigilance required for regions with comparatively less immuno-oncology experience.
- Restrictions related to COVID-19 impacted site activation, recruitment, and monitoring activities.

RESULTS

The Medpace team was able to efficiently conduct feasibility and site selection processes to identify high quality sites across the globe.

Medpace's experience in immuno-oncology permitted us to work in all regions globally targeted and support implementation of processes to ensure patient safety was maintained and irAEs were quickly identified and managed by sites.

Study activities were maintained despite COVID-19 related restrictions and overall recruitment targets were met. Database lock occurred on-time with a high level of SDV.

THE SOLUTIONS

- Medpace has existing site relationships across the globe that support rapid site identification and selection.
  - Site Relationship Coordinators in many countries allow Medpace to maintain close relationships with sites and expedite site selection and feasibility processes.
  - Medpace worked closely with local associates and the Sponsor to identify, qualify, and select sites to support efficient site selection.
- Medpace has worked extensively with immuno-oncology and plans in advance for potential irAEs, including site training and safety oversight. Our goal is to implement proactive mitigation strategies to decrease incidence of high grade events.
  - The Medpace team included experts in immuno-oncology who provided additional training for sites and CRAs and who provided guidance on management of irAEs, as needed.
  - Targeted training was provided to sites with less immuno-oncology experience compared to other sites globally.
  - irAEs did occur, but through appropriate site training, severity of events was minimized and events were appropriately managed per protocol.
- Use of existing site relationships and capabilities for virtual monitoring allowed Medpace to continue working with sites globally despite COVID-19 restrictions to ensure site start-up, activation, recruitment, and data cleaning continued.
  - Implementation of virtual monitoring globally (where allowed per local regulation) allowed CRAs to continue monitoring and maintain oversight of sites. This included sites that historically did not allow virtual monitoring prior to COVID-19. In these cases, Medpace leveraged our relationship with sites to accommodate virtual visits.
  - Medpace worked with the Sponsor and sites to minimize impact of COVID-19 on patients to help reduce missed study visits and assessments.