Case Study:

NAVIGATING REGULATORY AND OPERATIONAL CHALLENGES IN ASIA PACIFIC



MEDPACE WORKED ON A GLOBAL PHASE 1/2 SOLID TUMOR STUDY WITH A STRONG PRESENCE IN THE ASIA-PACIFIC REGION.

490 PATIENTS — **Phase 1 –** 440 patients; **Phase 2 –** 50 patients

49 SITES

6 COUNTRIES — Australia, Canada, France, Japan, South Korea, US

SERVICES PROVIDED

- Clinical Operations
- Regulatory Submissions
- Start-Up Services
- Medpace Reference Laboratories
- Data Management
- Statistical Analysis
- IRT

CHALLENGES

- Unique regulatory requirements in S. Korea and Japan
- Managing the study across multiple time zones with US-based Sponsor
- Ensuring appropriate cohort management to align with country-specific requirements

RESULTS

- The Medpace team successfully worked with the Sponsor to respond to queries from the Regulatory Authorities and maintain expected timelines for site activation and subsequent protocol amendment approvals.
- Medpace worked with local associates and developed processes to ensure timely communications to sponsor and sites globally, thus supporting robust study participation and enrollment in the Asia-Pacific region.
- Patients successfully enrolled to meet country-specific requirements – including enrolling patients in Japan at specific dose levels during dose escalation and in dose expansion combination cohorts and restrictions on which dose levels patients in South Korea could enroll.
- Enrollment in these countries met or greatly exceeded enrollment expectations.

THE SOLUTIONS

- Medpace has existing site relationships throughout the Asia-Pacific region and globally that support timely site activation. Medpace has local associates that serve as in-country subject matter experts on local Regulatory Authority and IRB/EC processes.
    - Medpace provided a detailed list of required documents to support submission of the initial protocol and protocol amendments along with due dates to support submission timelines.
    - When queries were received, Medpace worked with regulatory agencies to clarify the questions and proactively provided guidance on appropriate responses. Medpace supported the Sponsor in finalizing responses and preparing country-specific addenda, as needed.
    - Additionally, for this client, in another program, Medpace successfully hosted and supported inspections with multiple Asia-Pacific Regulatory Authorities.
- Medpace developed robust communication and cohort management plans to ensure smooth and timely communications from the global team to the Sponsor based in the US.
    - Expectations for issue escalation and expected timelines for responses were clearly established at study start.
    - Expectations for slot request and enrollment review processes were clearly communicated to sites at site activation to help ensure the US-based sponsor had time to review during their normal business hours. Timelines for the Asia-Pacific region were built to include time for translations, as needed.
    - Medpace Medical Monitors based in the Asia-Pacific region supported local teams during local business hours to ensure appropriate coverage for all regions.
- Study plans and site communications were modified at the global and country-level to ensure local enrollment requirements were followed.
    - Slots were held at specific dose levels for patients in Japan to ensure country-specific requirements were met. This was supported by developing study plans prior to site activation and ensuring clear communications to all sites globally.
    - Study enrollment forms and study plans were modified to reflect country-specific restrictions to help ensure patients were not enrolled into cohorts that were prohibited by Regulatory Authorities.