SAFETY EXPERTISE LEADS TO FDA APPROVAL FOR CUSTOMER COMPOUND

SITUATION

inVentiv Health Clinical was providing a client with drug safety services for an oncology compound development. The customer tasked inVentiv Health Clinical with 10 studies spanning Phase I-III.

CHALLENGE

To provide excellent service admist a fluctuating client environment, frequent protocol changes and additions, and large number of SAEs.

APPROACH

The inVentiv Health Clinical team, which had established an excellent relationship with the customer team from the start, worked proactively to manage the high-volume of SAEs, inconsistent data forms and changing deliverables. At the project's peak, inVentiv Health Clinical was managing a very high volume of SAEs – 730 (initial and follow-ups) per year. As the number of protocols expanded, the SAE volume increased as well as the deliverables for the project.

It became apparent that SAE forms were not designed to capture information needed for some of the newer studies. The inVentiv Health Clinical safety team worked with the customer to develop a strategy and establish procedures to obtain the needed information from the investigator sites.

Throughout the project, the customer received requests from the FDA for additional safety information. inVentiv Health Clinical was quick to respond to these ad-hoc requests and deliver what the customer needed to facilitate a desired outcome.

The team assigned to the project was consistent, with minimal change in leadership for the life of the project. Communication between inVentiv Health Clinical and the client was frequent, open and collaborative.

WINNING PLATFORM

After approximately five years of development, the oncology product received FDA approval and post-approval work is ongoing. The client has commented, *"You have played a significant role in bringing [the product] from its earliest developmental stages to approval for use in cancer patients who have very few other options. That is a something to be really proud of ...! Thanks yet again for all of your consistent work these past years which has played an important role in helping us get [the product] approved."*

CASE STUDY

Therapeutic Area
Oncology

Indication
Multiple Myeloma

Outcome Highlights
Phase I-II

Patient Population
Patients with multiple myeloma who had received at least two prior therapies.

Services

- SAE/Medical Monitoring
- Safety Reporting
- SAE Safety Narratives
- Safety Databases

ABOUT INVENTIV HEALTH CLINICAL

inVentiv Health Clinical, formerly PharmaNet/i3, is a leading provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies. With 7,000 employees in more than 36 countries, inVentiv Health Clinical offers therapeutically specialized capabilities for all phases of clinical development, bioanalytical services, and strategic resourcing from a single clinical professional to an entire functional team.