Case Study:

ADVANCING PATIENT SAFETY: GLOBAL FIH STUDY ON ADCS FOR ADVANCED SOLID TUMORS

Medpace worked with a biotechnology group on a global FIH study with an Antibody-Drug Conjugate (ADC) in patients with advanced solid tumors.

100 PATIENTS

31 SITES

4 COUNTRIES
Netherlands, Spain, UK, US

SERVICES PROVIDED

- Clinical Operations
- Medical Writing
- Regulatory Affairs
- Safety & Pharmacovigilance
- Start-up Services
- Medpace Reference Laboratories

CHALLENGES

The ADC was designed with a goal of reducing ADC toxicity, but its payload had a known risk of ocular toxicities. The protocol had appropriately prepared for infusion related reactions (IRRs) and included ophthalmologic evaluations.

RESULTS

The Medpace team was able to successfully support implementation of processes to ensure patient safety while continuing development of the ADC.

THE SOLUTIONS

Medpace has worked with novel ADCs and prepares in advance for potential toxicities, be it ocular, IRRs, left ventricular ejection fraction, etc., enabling proactive site training and safety oversight. Our goal is always to detect these issues early and implement proactive mitigation steps to decrease their incidence and severity, thus allowing the development of the asset to continue apace.

- Medpace worked proactively with the sites and the Sponsor to ensure ocular prophylaxis was implemented for all patients, including mandatory ocular exams and the use of steroid and vasoconstrictive eye drops, and provided guidance for the management of ocular toxicities, should they occur.
- The inclusion criteria were tightened to exclude patients with any keratitis.
- IRRs did occur, and with the SRC, a prophylaxis regimen was developed which maintained a low IRR incidence rate and severity throughout the study.