

KCAS Bioanalytical & Biomarker Services is a contract research organization (CRO) with 35+ years of bioanalytical and immunoanalytical expertise. We specialize in the development and validation of robust small, large molecule and biomarker methods for discovery, preclinical and clinical studies.

Supporting a Phase I Program Conducted in Australia

Challenge

KCAS conducted the preclinical bioanalytical program in animal species for a small molecule, international pharmaceutical company pursuing a 505(b)(2) path of approval. As the program moved into human studies, the client intended to perform the first in human clinical studies in Australia, followed by Phase II/III clinical efficacy studies in North America. The client was initially concerned about sample shipment and timelines.

Results

KCAS validated the human bioanalytical method ~ 9 months prior to study start, establishing ample long term matrix stability before the study started. KCAS provided clinical sample handling instructions to the Sponsor and the Clinical CRO, and closely coordinated the sample shipping, providing additional resources to track and shepherd samples through US customs. Samples moved through US customs, and were received in good condition. Sample analysis proceeded immediately, and data was provided ahead of the initial timelines estimated.