RECRUITING PATIENTS WITH IMPAIRED RENAL FUNCTION

OVERVIEW
According to FDA Draft Guidance published in March 2010, a pharmacokinetic (PK) study should be conducted in patients with impaired renal function when the drug is likely to be used in such patients and when renal impairment is likely to mechanistically alter the PK of the drug and/or its active metabolites. One example of this is if the drug or a principal active metabolite is eliminated renally. This is also a consideration if a drug is metabolized through the liver because renal impairment may inhibit certain pathways of hepatic and gut drug metabolism. As a result, a PK study in patients with renal impairment should be conducted for most drugs intended for use to treat chronic disease.

The study evaluated the tolerability, pharmacokinetic and pharmacodynamic effects of a treatment of secondary hyperparathyroidism after a single dose administration to patients with mild, moderate and severe renal impairment (not requiring dialysis), and a control group (age and gender matched normal healthy volunteers). The strategy was to evaluate the effect of the compound on an equal number of patients with different stages of impaired renal function.

CHALLENGE
A restrictive protocol made it difficult to recruit study volunteers; finding patients with moderate/severe renal impairment who met the strict inclusion/exclusion criteria of the study presented the major challenge to completing enrollment. Patients also needed to be confined for approximately 62 hours (or three nights) followed by three consecutive daily outpatient visits during the winter holiday period.

SOLUTION
inVentiv Health Clinical overcame the recruitment challenge by considering new nephrology data from the sponsor that allowed the study criteria to be less restrictive. inVentiv Health Clinical initiated discussions with key opinion leaders in nephrology to review and analyze the data which led to the amendment of inclusion/exclusion criteria to facilitate recruitment while preserving the integrity of the trial.

Through hospital collaboration, inVentiv Health Clinical had access to extensive academic knowledge, in depth expertise in nephrology and to the necessary patients. inVentiv Health Clinical developed a strategy for working with investigators and the institutional Review Boards (IRBs) to support recruitment and the IRB review process which included a protocol presentation to the IRB by one of our Medical Directors.

RESULTS
inVentiv Health Clinical was able to overcome the recruitment challenges and enroll the patients by utilizing our in-house expertise and through collaborating with the hospital, sponsor, and key opinion leaders in nephrology. Through this collaboration an amended protocol was developed, which when combined with a specially designed recruitment strategy, allowed for the successful completion of the study.

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.

CASE STUDY
Study Type
PK/PD study in renal impaired patients

Indication
Secondary Hyperparathyroidism

Clinical Phase
Phase I

Patient Population
Patients with moderate to severe renal impairment

Participating Countries
Canada

Services
• Clinical Laboratory Evaluation
• Protocol Development
• Data Management
• Medical Monitoring
• Medical Writing
• Patient Recruitment
• Project Management
• Regulatory
• Safety Reporting
• Site Management/Clinical Monitoring