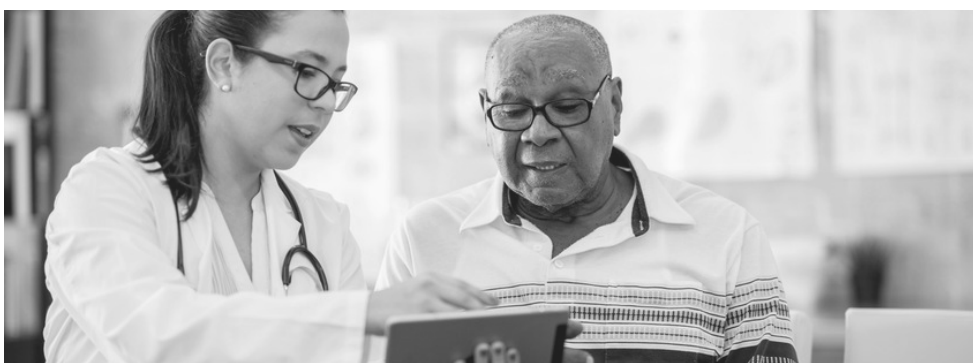




research work; carry  
into the causes of cancer  
successful.  
**re·search<sup>2</sup>** /rɪˈsɜːtʃ/  
make a detailed study of  
(something): She is researching  
re·search·er n a person who  
researches



**Novum**  
PHARMACEUTICAL RESEARCH SERVICES

# CASE STUDY

COMPLEX EARLY PHASE CLINICAL CONDUCT TO  
SUPPORT AN INNOVATIVE NDA PROGRAM

## OVERVIEW

Novum was selected by a pharmaceutical company seeking a quality CRO partner to execute a double-blind, placebo-controlled, single-ascending dose study to assess the safety, tolerability and pharmacokinetics of three dose levels of a novel oral formulation of a drug administered to three cohorts of healthy subjects.

## OBJECTIVES

Evaluate a new patented platform drug delivery technology of a traditionally IV-only infectious disease medication by studying the safety, tolerability, characterization of the pharmacokinetic profile, and an assessment of the effect of food on pharmacokinetics of three levels of ascending doses.

## CHALLENGES

- Complex study design, where single ascending dose (SAD) and food effect studies are combined in a single study.
- Higher screen failure rates due to restrictive entry criteria.
- Multiple assessments (physical, lab, clinical, including comprehensive otologic and audiometry assessments) occurring simultaneously.
- Multiple matrix (plasma, urine, and fecal material) collection and processing at our clinic.
- The decision to proceed to the next higher dose administration (or to proceed to repeat the same dose under fed conditions) following review of all pertinent blinded safety drug concentrations, and safety and tolerability data.
- Tight timeline for the study.

## NOVUM'S APPROACH

Novum's study team and dedicated IRB worked closely with the study sponsor and safety monitoring board to ensure study success. Novum increased staffing and oversight including extensive investigator involvement and monitoring. Also, it collaborated with an outside audiometry facility for comprehensive hearing assessments and added physical assessments during study conduct as new pre-clinical information became available. Finally, Novum presented information on the patient data to the sponsor and highlighted the benefits that it would bring to the study, including the ability to access near real-time data.

## RESULTS

- Quick enrollment
- Real -time data
- Pharmacokinetic and statistical analyses delivered ahead of schedule
- Competitive completion time
- Allowed the sponsor to make decisions quickly and easily
- Study successfully met all objectives
- **The sponsor was extremely pleased and it has outsourced to Novum subsequent studies within the program**