



## CASE STUDY



**EMERALD**  
CLINICAL TRIALS

# Emerald Clinical's Scientific Leadership Model Proves Critical to Meeting Difficult Recruitment Targets in Atypical Phase I Study of a New Renal Drug

Having a well-respected clinician as part of the team to communicate the scientific value of the research gave valuable credibility and comfort level to referring physicians.

## SITUATION

Emerald Clinical was contracted by a mid-size pharmaceutical company to conduct project management and clinical monitoring in a study to evaluate the pharmacokinetics (PK) and safety of a sulfated oxysterol in subjects with impaired kidney function and matched control subjects with normal kidney function. Phase I of this study was atypical in seeking patients who were already sick, for research on a drug being used for the first time with no prior benefits proven.

Emerald Clinical's scientific leadership model was a significant advantage in this unique situation. The level of trust created with this peer-to-peer communication model has multiple benefits for sponsors, research teams, participating physicians and patients. The scientific integrity of studies is protected, physicians are more willing to recommend studies when a fellow clinician is on the team, and there is a greater likelihood of recruiting optimum patients for the study who will be most likely to stay engaged to conclusion. In addition, patient needs and concerns are understood and addressed more adequately by those who have been involved in the day-to-day care of people with their conditions.

## CHALLENGES

Recruitment for this Phase I study was particularly challenging as it was the first time the drug was being used, with no research to show if there would be benefits to using it. Furthermore, recruits would be patients who were already sick. In addition to being inherently difficult to recruit, there was also no adequate financial reimbursement available.

## SOLUTIONS

It is important in situations such as this to be able to work closely with the physicians who could potentially be recommending patients for the study. Emerald Clinical scientific leader and renal clinician Martin Gallagher was able to set up a referral network of five nephrology practices to work hand in hand with doctors who would potentially be recommending patients for the study, engaging them scientifically to make them aware of why this study was important and how it could help advance treatment options in the future.

Professor Gallagher's ability to communicate with referring nephrologists and give them a comfort level of the importance of the study and the care for their patients during the study was integral in overcoming this challenging recruitment.

## RESULTS

With a well-respected clinician as part of the team to help set up referral networks and communicate the scientific value of the research to participating physicians, Emerald Clinical was able to meet the recruitment targets and facilitate successful completion of the study.

### Clients Benefit from Emerald Clinical's Scientific Leadership Model

The Emerald Clinical Scientific Leadership model offers a scientifically sound, pragmatic approach that informs strong operational delivery and protocol alignment with clinical practice. We provide a framework that enables active peer-to-peer communication and action pathways between global scientific committee members, national scientific leaders and principal investigators. Our team possesses a deep understanding of the clinical landscape and emerging trends in clinical practice. The unique insights from a real-world clinical perspective this adds to studies leads to greater engagement, greater number of sites recruiting, lower screen fail rates and higher retention of patients for our clients, as well as a greater level of comfort and input from participating physicians and recruits.



**EMERALD**  
CLINICAL TRIALS

[emeraldclinical.com](http://emeraldclinical.com)