ERGOMED

Case Study

# In the Face of Adversity

## Flexible clinical trial strategies for small biotech companies

### Visual Snapshot

**Clinical Trial**
Combination phase I/II trial in the treatment of advanced clear cell renal cell carcinoma (RCC)

**Condition**
RCC

**Purpose**
Evaluate the efficacy of a new oral CXCR4 inhibitor in patients with RCC

**Patient-Type**
Second-line kidney cancer patients (based in the U.S.)

## Ergomed's solutions to the challenges of clinical trials

Even with best-laid plans, the introduction of an unexpected factor can have a devastating effect on your entire strategy. In an environment like this, you need a clinical research organization (CRO) that knows the intricate details of the industry and has the flexibility and agility to make quick, strategic changes whenever necessary.

### The Challenge

**A new company facing a costly delay**
A small biotech startup needed to evaluate the safety and efficacy of its first drug: a new oral CXCR4 inhibitor for patients with advanced clear cell renal cell carcinoma (RCC). However, it did not have the resources or operational knowledge necessary to advance quickly and needed expert support from a CRO to help them to the next stage.

### The Strategy

**Developing a new strategy quickly**
The proposed solution was a sister study that would run concurrently with the original protocol. Using a subset of the sites already in start-up, the sister study would target a slightly different RCC population and combine its investigational product with the newly approved secondline regimen. Time was a major factor when assessing the feasibility of launching a new study.

**Creating time efficiencies**
By reviewing the previously submitted feasibility surveys, Ergomed was able to identify a subset of potential sites to participate in an abbreviated feasibility for the new study.

### The Outcome

In the face of devastating news, the small biotech company's lack of internal resources and experience could have meant the dissolution of the company. However, Ergomed's ability to think creatively and work efficiently allowed both clinical studies to launch on time. By duplicating efforts on the sister study, all four sites were launched in less than six months, a remarkable achievement considering average academic institution lead times. The study enrolled a total of nine patients and obtained valuable data for steering the direction of the company's clinical development program. An unexpected delay could have meant disaster for this small startup. Ergomed was able to give these companies the support and edge they need to not only survive, but thrive.