5 Questions to Anna Baran, head of Trial Execution Consulting and Chief Medical Officer, KCR

KCR's new service – Trial Execution Consulting (TEC) – has been included in the company portfolio for more than half a year now. How the service is developing, what are the main issues TC covers, and what are the team greatest accomplishments? Anna Baran has the answers.

1. **Why is consulting expertise needed in today's clinical trial environment?**

   The clinical trial environment has shown increased complexity over the years. At first glance, one would attribute this to innovation in molecules (new enzymatic pathways and target receptors, or evolution of therapeutic areas). In our view however, this is relatively easy to absorb and implement from a service provider's perspective.

   The real issue emerging is that there is a shortage of space to run trials in conventional ways. Patient populations are growing, but the site pool has plateaued. Additionally, regulatory agencies are announcing initiatives to increase efficiency of drug development by optimizing capabilities in modelling and simulation of high-quality data in decision making. Consulting services help to operationalize these innovative and modern concepts of drug development.

2. **What are the main problem areas that TEC covers?**

   Our services for the near future are designed for stable, controlled expansion. Now, most of our projects are focused on optimizing trial protocols through targeted landscaping and feasibility studies. Additionally, we work hand-in-hand with our Project Management teams to support initial stages of project delivery, investigator communications and agency interactions. The last coverage area is routine drug development consulting, where we step into early stages of clinical development to help our clients build strategies for pivotal trials.

   Overall, we deliver services while maintaining strong CRO roots and mindsets, which allows us to stay close to the ground when proposing solutions. We also demonstrate a continuous money consciousness, as we understand the difficulties that clients endure when facing an unexpected round of financing.

3. **What has been some of this service areas greatest accomplishments?**

   We are still very young, but I am proud to say that we recently supported a worldwide feasibility project on a monotherapy trial of anty-PD-1 in a niche patient population. Furthermore, we checked a pan-European development oversight towards a very complex, non-standard vaccine study. Both projects were successfully advanced to recruitment stage and both are assumed to respond to emerging health threats as listed recently by WHO.

Of course, we are impatiently awaiting the outcomes of these trials, as only at that stage we will know if certain scientific assumptions were rightfully made. In addition, we often help US-based companies implement their programs in Europe or design bridging studies. These services follow the longstanding tradition of KCR, as we started as EU company and further advanced to the US market.

4. **What type of clients do we have working relationships with in TEC?**

   Biotech or biopharma companies, as they are quite often very self-critical, and thus willing to engage with external expertise. TEC usually meets these clients in the early stages of phase 2 or phase 3 planning, when a company is estimating the capital required to run their development program and then we begin our partnership.

5. **What do you expect for the future of Trial Execution Consulting?**

   First, we need to prepare to adopt several new industry initiatives and solutions. We will surely strive to stay in the loop of developmental medical knowledge, however we also must always be a step ahead of regulatory science developments. ATMPs, nanotechnologies and the concept of engaging artificial intelligence in decision making will pose an obvious challenge to us. We cannot forget about emerging health threats, so we will continue our work in immune oncology, anti-infectives and vaccines, all to support our broadly defined patient populations. This is the vision, to be verified by reality. Let us keep fingers crossed!

KCR is a contract research organization providing clinical development solutions for the pharmaceutical, biotechnology and medical device industries.
The company supports clients with full-service capabilities across three main services: Trial Execution (TE), Functional Service Provision (FS) and Trial Execution Consulting (TC) over a broad range of therapeutic areas.
KCR operates across four main regions: North America, Western Europe, Central Europe, and Eastern Europe with hubs located in Boston, U.S., Berlin, Germany, Warsaw, Poland and Kiev, Ukraine. KCR's geographical locations allow for optimized delivery of trial execution strategies to develop life-changing therapies. For more information visit www.kcrcro.com.
KCR: We see human behind every number.