Clinical trials, with their complexities specific to every study, present different challenges to be overcome by Clinical Research Organizations (CROs). There are various factors that might have a negative effect on a study execution, including poor patient enrollment rate, trouble contracting sites, submission failures, “one-size-fits-all approach” or related lack of flexibility, time delays deteriorating profitability, inefficient communication, and many others.

IS YOUR STUDY’S SUCCESS IN JEOPARDY? KCR’S COMPREHENSIVE RESCUE SUPPORT WILL EXPEDITIOUSLY STEER IT BACK ON TRACK
Taking over each rescue study on a case-by-case basis, our dedicated team of experts quickly analyze its status and provide accurate solutions to steer it back on track in a timely manner maintaining its safety, efficacy, and validity.

IRRESPECTIVE OF THE FACTORS BEHIND YOUR DISSATISFACTION WITH THE STUDY, IF YOU FIND IT MIGHT BE AT RISK, KCR OFFERS YOU A UNIQUE AND RELIABLE RESCUE PACKAGE.

RELIABLE PATIENT RECRUITMENT PROCESSES

Patient enrollment is one of the biggest hurdles in the clinical trials market. According to research 11% of sites in a given trial typically fail to enroll a single patient and 37% under-enroll their targets (Source: Tufts CSDD, 2013).

KCR has a track record of success in managing studies which were in danger of not being completed because of poor subject enrollment. Our high efficiency in patient recruitment is the result of reliable recruitment methods applied while selecting subjects. KCR’s professionally trained team is successful with recruitment of challenging patient populations and excels at resolving study difficulties.

Providing Europe-wide coverage, KCR has comprehensive knowledge of the region. Our local regulatory affairs experts maintain constant intelligence across European countries, assuring operating based on most up-to-date regulations, as well as seamless communications with competent authorities and ethics committees.

This, coupled with access to regional networks of investigators and patients, streamlines any rescue project implementation taken over by KCR.

KCR RECRUITS ON TIME, OR EVEN AHEAD OF SCHEDULE IN MORE THAN 90% OF TRIALS CONDUCTED.
COMPETENT AND DEDICATED RESOURCES

Efficient communication and building trust with a Sponsor’s team dissatisfied with their previous CRO, is crucial to embark on a successful project rescue. KCR’s highly qualified and dedicated team demonstrates a high level of professional communication supported by vast medical background and scientific research experience (29 Medical Doctors and 25 Ph.Ds.).

Time is of utmost importance in any clinical study, and especially in a rescue project which is already behind. KCR’s experts will seamlessly integrate into your project to concentrate on fast and proper identification of study obstacles and apply efficient corrective management strategies. This approach includes proper risk assessment and risk mitigation plans.

KCR’S EXTENSIVE RESCUE STUDY EXPERIENCE ALLOWS US TO ENTER A PROJECT AT ANY STAGE, MEETING ENROLLMENT NEEDS AND DELIVERING HIGH QUALITY DATA TAILORED TO THE SPECIFIC REQUIREMENTS OF YOUR TRIAL.

FIT FOR PURPOSE RESCUE PLAN

Solutions tailored to fit a specific study, developed on project-by-project basis are crucial in rescue trials. Key aspects of KCR’s efficient rescue process include high level feasibility assessment and an accurate study budget to enable our Sponsors to plan their expenses ahead.

KCR managers will apply the most efficient time and money saving strategies to ensure the challenges on each stage of the study execution are properly addressed. Our adequate local insight ensures a successful assessment of the study rescue potential.
Multiple pharma companies often favor Western Europe and the U.S. over other regions for clinical trials. However, numerous challenges related to keeping timelines, prolonging recruitment periods and exceeding budgets make Sponsors consider other solutions as well.

KCR rescue services include the Central & Eastern Europe (CEE) and Commonwealth of Independent States (CIS) countries as rescue recruiters providing successful finalization of the enrollment within limited timelines, while achieving good quality data to the Sponsor’s satisfaction.

→ A large, international, multicenter, double-blind, placebo-controlled, phase III project concerning patients suffering from Diabetic Foot Ulcer of Neuropathic Origin;
→ Difficulty in enrolling patients due to poor recruitment in Western European countries such as Germany, Belgium, the Netherlands, Denmark and Sweden;
→ Study timelines delayed by 18 months under another CRO’s management.

Over the last 15 years KCR has been entrusted with a significant number of rescue studies. During this time KCR has successfully earned an expert reputation and thus developed a reliable rescue process.

KCR IS AN EXPERT RESCUE STUDY PROVIDER WITH A PROVEN TRACK RECORD OF SUCCESS IN EXPEDITIOUS RECRUITMENT OF WIDE PATIENT POOLS AND EXTENSIVE EXPERIENCE ACROSS A WIDE RANGE OF THERAPEUTIC AREAS.

CASE STUDY 1: PHASE III RESCUE DIABETIC FOOT ULCER STUDY

BACKGROUND:

→ Fast development of an efficient rescue study execution plan;
→ Obtaining regulatory approvals in additional countries in limited timelines;
→ Contracting additional sites and facilitating their smooth incorporation in the study;
→ Completing recruitment as soon as possible without any further delays.

TRACK RECORD OF SUCCESS: CASE STUDIES
CASE STUDY 2: PHASE II RESCUE BIOEQUIVALENCE TRIAL IN MYELODYSPLASTIC SYNDROME

BACKGROUND:

- Significant obstacles with recruitment into a bioequivalence study in the U.S. concerning patients suffering from Myelodysplastic Syndrome (MDS)

REScue SOLUTIONS:

- Comprehensive support proposed by KCR for this study in 1 CEE country (Poland) – included project management, set-up, registration, IMP preparation/importation, local comparator purchase, site selection, clinical monitoring, logistics, legal and financial services and vendors’ management
- Effective project management and set-up process provided by 1 Regional PM, 1 Regional Lead CRA, 2 CRAs and 1 CTA (plus 2 local managers supporting process);
- Close collaboration with hospital lawyers to achieve consensus regarding providing comparator to the sites;
- Special warehouse - IMP Depot - selected, audited and contracted to facilitate the study drug flow;
- Well-organized and effective Investigators Meeting for 10 investigators for training and set-up purpose (1 day) and the CRA Training for CRO staff (1 day)
- Close cooperation with Sponsor’s team (excellent communication with the Sponsor representative);
- Supportive approach and pro-active involvement in collaboration with vendors.

RESULTS:

- Recruitment of 106 patients in 16 investigational sites (25% of the total recruitment goal) within limited rescue recruitment timelines;
- KCR appointed the managing CRO for the whole program, which involved 75 investigational sites across 13 European countries: Belgium, Bulgaria, Croatia, the Czech Republic, Denmark, France, Germany, Hungary, Italy, the Netherlands, Poland, Slovakia and Sweden.
- KCR finalized the study on time and within the agreed budget, to the Sponsor satisfaction. Thanks to contracting the sites in the CEE region, recruitment was significantly boosted and completed in six months.

CHALLENGES:

- Randomizing 28 remaining patients in 6 months;
- Challenging and complex process of sites’ contracting, due to intricate procedures provided by the protocol and reimbursement issues;
- Demanding study registration process, including IMP import from the U.S. to Poland;
- Individual training requirements – study procedures and study drug requirements;
- Close and intensive monitoring due to both short and intensive treatment;
- Very tight timelines due to huge project delay in the U.S.;

RESULTS:

- Competent Authority (CA) approval granted on time, without substantial questions;
- Contracts with investigators and study sites were discussed, agreed and signed for 5 investigational sites according to assigned timelines;
- Feasibility, site selection process, registration process, Investigators Meeting and sites initiation process performed according to requirements and on time;
- Recruitment completed 3 months ahead of schedule;
- All data for statistical analysis collected one month after LPLV;
- 2 additional projects awarded to KCR upon successful finalization of the rescue study.
KCR: EXCELLENCE IN CLINICAL TRIALS SINCE 1997

KCR is a Contract Research Organization (CRO) with a dynamic team of over 300 professionals operating across 19 countries in Europe as well as the U.S. With 18 years of experience, almost 400 trials executed, 35,000 patients recruited and over 3,000 sites contracted, KCR is a strategic solutions provider and a reliable alternative to top tier CROs, delivering the all-important flexibility.

We provide services on long standing contracts to 12 out of the Top 20 Global Pharma companies, as well as biotech firms from Europe, Israel, and the U.S.

KCR offers full service capabilities via three types of professional product lines:

- Trial Execution
- Functional Service Provision (FSP)
- Late Phase

KCR: WE SEE HUMAN BEHIND EVERY NUMBER.

18 18 YEARS OF EXPERIENCE

400 400 CLINICAL TRIALS EXECUTED

3,000 ALMOST 3,000 SITES CONTRACTED

30,000 OVER 30,000 PATIENTS RECRUITED

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