

KNOWLEDGE TO RECRUIT
KNOWLEDGE TO RETAIN

SMART COUNTRIES SELECTION AND EFFECTIVE PROJECT MANAGEMENT LEAD TO 100% OF RECRUITMENT ON TIME

 BACKGROUND

A **clinical endpoint study** to prove **bioequivalence** of a topical agent administered in adult patients suffering from Knee Osteoarthritis. The study involved **a full scope of services**, including Feasibility and Site Selection process, Sites Set-up and Contracting, Study Authorization, Clinical Monitoring, Medical Monitoring, as well as Data Management and Project Management.



 CHALLENGES



Recruitment target of **1200 patients** to be achieved within a **9 month recruitment period**



Timely drug import from US to EU and Ukraine, including obtaining drug import licenses



Intensive monitoring



Communication with **large study team**: 250 Investigators, Nurses and Coordinators

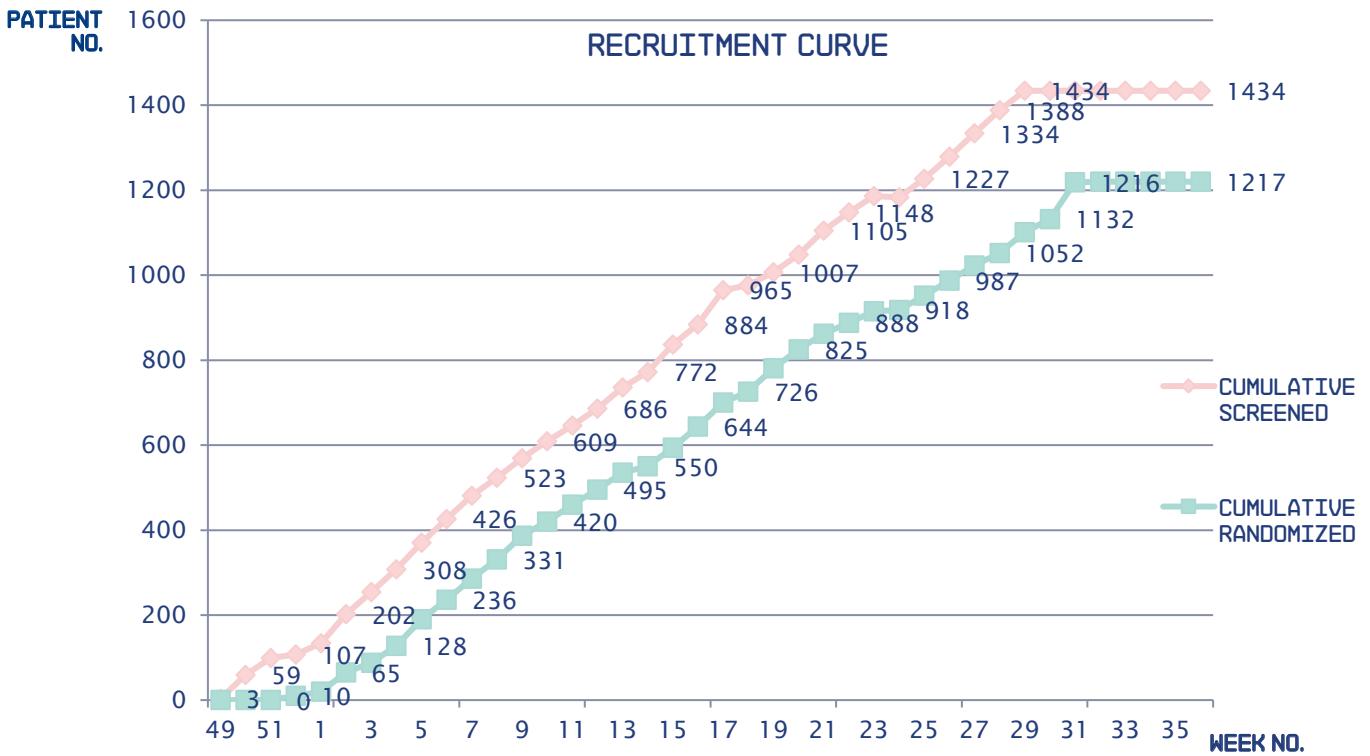
 SOLUTIONS

- **4 CEE countries** selected for the project execution, with vast recruitment potential and relatively low GDP per capita: **Poland, Hungary, Romania and Ukraine**
- **Careful sites selection process**, choosing motivated investigators with capacity to enroll large number of patients in parallel
- **Effective project management** and set-up process, leading to no delays in sites activation
- Investigators' meeting for investigators from 4 countries and **efficient trainings**
- Regular **thorough clinical monitoring**, ensuring proper quality of data
- Implemented **24/7 operational execution management style**
- Close operation with Sponsor's team from US



RESULTS

- ➔ 1434 pts screened/ 1217 pts randomized - **100 % recruitment goal met on time**
- ➔ Screen failure rate significantly lower than initially assumed
- ➔ 41 contracted and actively recruiting sites within 4 countries
- ➔ Contracted milestones achieved on time



TOOLS

OPERATIONAL

- | SITE MANAGEMENT BOOSTER TOOLS
- | LESSONS LEARNT MEETINGS
- | REFERRALS

RESOURCING

- | SITE COORDINATOR
- | NURSES/OTHER RESOURCES, ACCORDING TO NEEDS
- | EXTERNAL DATABASE SEARCH

MARKETING

- | MARKETING MATERIALS
- | MEDIA CAMPAIGNS
- | STUDY BRANDING

KCR is a Contract Research Organization (CRO) providing strategic clinical development solutions for the pharmaceutical, biotechnology and medical device industries. We have the knowledge to recruit and the knowledge to retain patients. Our successful approach combines KCR's geographic coverage and a portfolio of sophisticated recruitment tools that allow us to approach the most challenging projects with confidence.

For more please visit www.kccro.com or contact us at info@kccro.com

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