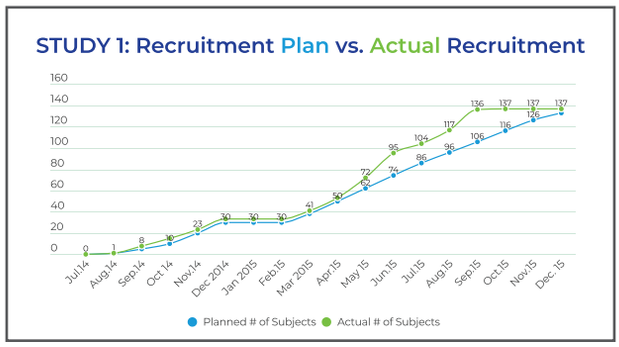
QPS
CUSTOM-BUILT RESEARCH™

CASE STUDY
ACCELERATING ONCOLOGY TRIALS FOR FDA AND EMA APPROVAL

A quickly growing biotech approached QPS with an urgent need to perform two multinational Phase III trials in Prostate Cancer patients, designed to collect the efficacy and safety data required to submit to the FDA and EMA. As the global, full-service CRO, QPS oversaw study conduct at all of the clinical study sites across the USA, Europe and Asia.

TRIAL #1: EXCEEDING ENROLLMENT EXPECTATIONS

The first trial aimed to enroll 133 patients over 18 months across the US, EU and Asia. QPS exceeded these expectations by enrolling 137 patients across 26 active study sites in eight countries within just 13.5 months—4.5 months ahead of schedule.

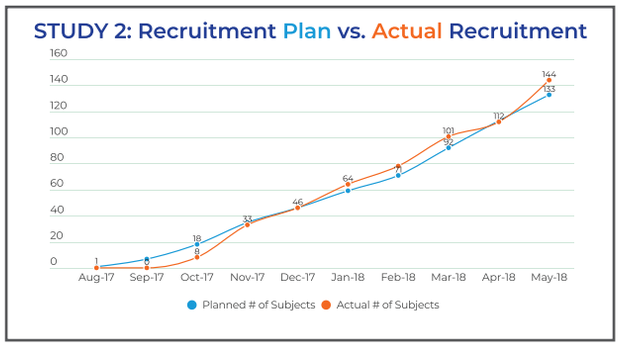


KEY TO SUCCESS: STRATEGIC SITE SELECTION AND STRONG RELATIONSHIPS

QPS's success in Trial #1 was driven by strategic site and investigator selection. Our PMs prioritized building and maintaining close relationships with study investigators. This collaborative approach was instrumental in surpassing enrollment goals. Notably, four sites in Lithuania were critical, enrolling 77 of the 137 patients. Targeting the Baltic states not only reduced costs but also provided critical treatment access to patients who might otherwise have lacked options.

TRIAL #2: EXPANDING SUCCESS IN ASIA

For the second trial, QPS was tasked with enrolling 140 patients, with a specific focus in Asia. Building on the success of Trial #1, QPS selected top-performing sites globally, adding South Korea to our Asian portfolio. 21 study sites were activated across five countries and three global regions. Our Lithuanian investigators played a pivotal role, sharing key strategies with South Korean sites, leading to a significant increase in Asian enrollment, with those sites contributing nearly 25% of the global monthly enrollment within four months.



OUTCOME: FDA AND EMA APPROVAL

The sponsor celebrated our achievements as we exceeded enrollment targets ahead of schedule. Independent audits praised the quality of the data collected, which played a crucial role in the FDA and EMA approval of the new prostate cancer drug. This success represents a significant advancement in prostate cancer.

Discover how QPS can accelerate your clinical research.

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- Site Selection & Monitoring

URO-ONCOLOGY KEY OPINION LEADER (KOL) NETWORK

EUROPE

- Dr. Mindaugas Jievaltas, Urologist | University Hospital Kaunas/Clinic of Modern Oncology | Kaunas, Lithuania
- Dr. Hilde Jalving, Oncologist | University Medical Center Groningen | Groningen, Netherlands
- Dr. Jeffrey Yachnin, Oncologist | Center for Clinical Cancer Studies at Karolinska University Hospital | Stockholm, Sweden
- Christina Junvik, Masters Biopharmaceutical Sciences | Early Drug Development in Oncology | Malmö, Sweden

USA

- Dr. Raoul Concepcion, Uro-Oncologist | US Urology Chief Medical Officer | Nashville, Tennessee
- Dr. Gordon Brown, Uro-Oncologist | Summit Health/New Jersey Urology | Voorhees, New Jersey
- Dr. David Sussman, Urologist | Summit Health/New Jersey Urology | Voorhees, New Jersey

APAC

- Dr. Yen-Hwa Chang, Uro-Oncologist | Taipei Veterans General Hospital | Taipei, Taiwan
- Dr. See-Tong Pang, Taiwan Urological Association Chairman | Chang Gung Memorial Hospital (CGMH) | Taipei, Taiwan

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