CASE STUDY
OPIOID USE DISORDER

Opioid use disorder (OUD) is a chronic mental health condition with serious and lifelong consequences ranging from distress and/or impairment to disability, overdoses, relapses, and death[1]. Both despite and because of the unrelenting human and societal tolls of the ongoing opioid crisis, the OUD market is forecast to be ever expanding in the foreseeable future[2].

MARKET SITUATION

Among the available treatment options for OUD, the buprenorphine segment holds the largest market share. Additionally, when categorized by route of administration, the parenteral route leads in market share[3]. This combination suggests an optimal strategy for entering the OUD market.

CUSTOM-BUILT RESEARCH PLANS

A quickly growing biotech client approached QPS with a request to perform four long-term preclinical studies of its product aiming to counter OUD.

The product, a new formulation of a currently marketed product indicated for OUD, featured a slow-release subcutaneous injection formulation that significantly reduces the dosage interval. This addresses the unmet patient needs of a long-term treatment and provides ease of access and assurance of compliance, thereby boosting the potential of improved and long-lasting success against OUD.

QPS designed a series of preclinical studies to collect the information required for IND application packages, which were submitted to secure approval for the next step, clinical trials. QPS, a global full-service GLP compliant CRO, designed and conducted this series of preclinical studies at the QPS Center for Toxicology and Pharmacology Services (CTPS) in Taipei, Taiwan.

CHALLENGES

The gravity of the opioid crisis created challenges:

- Strict quality requirements for approval studies
- Time sensitive study deadlines
- Exceptional attention to detail in all aspects of the studies including execution, documentation, and data analysis and reporting
- Technical challenges of testing a human subcutaneous formulation in non-human species
- Technical expertise required to address the 505(b)(2) regulatory challenge

SOLUTION

Pharmacokinetic and pilot studies, of durations lasting up to six months, were conducted to support the development of the formal toxicology studies. The toxicology studies were then designed to obtain the pharmacokinetic profile of the drug formulation. Technical insights were also carefully gathered to document administration of the drug in non-human subjects.

RESULTS

QPS delivered four GLP toxicology studies of the subcutaneous formulation, two in rodent subjects and two in non-rodent subjects, with increasing durations up to 10 months. These studies were completed on time and with great data accuracy, enabling the client to accurately and promptly submit the application for its Phase I trial and subsequent Phase II trial.

Discover how QPS can accelerate your clinical research.

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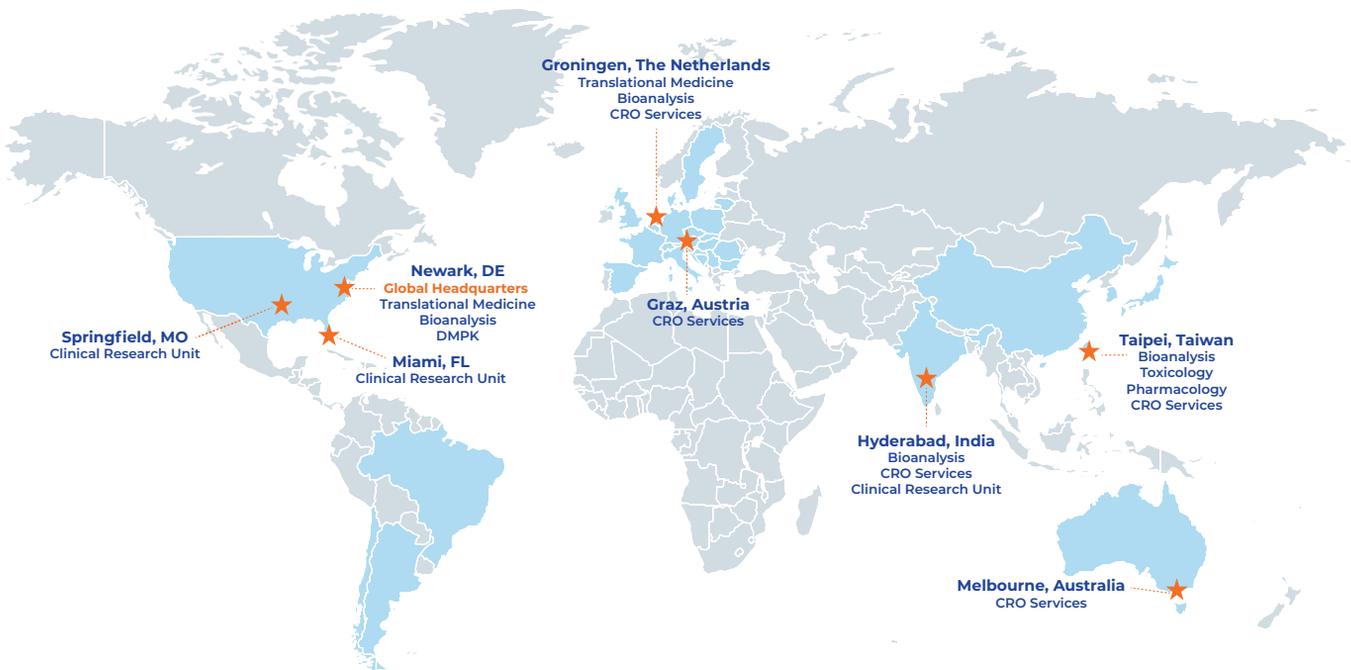
CLINICAL TRIALS SITE NETWORK LOCATIONS



NETWORK LOCATIONS: USA / Austria / Australia / Argentina / Belgium / Bosnia / Brazil / Bulgaria / Chile / China / Croatia / Czech Republic / Denmark/ France / Germany / Hungary / India / Italy / Lithuania / Netherlands / Poland / Romania / Serbia / Slovakia / South Korea / Spain / Sweden / Taiwan / United Kingdom

Pharmacology | Toxicology | DMPK | Bioanalysis | Translational Medicine | Phase I Clinics | Regulatory & Medical | Leukopak & PBMC

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