QPS
CUSTOM-BUILT RESEARCH™

A FLEXIBLE APPROACH TO **ONCOLOGY CLINICAL TRIALS**

WHEN YOUR FOCUS IS CLINICAL TRIALS,
QPS' global clinic network provides the ideal support for your Phase I - IV clinical trials from initiation through filing.

CANCER — A GLOBAL FOOTPRINT

Cancer continues to be a major cause of mortality worldwide, necessitating the ongoing need for clinical trials. However, clinical research in oncology presents a number of challenges. Multiple new agents are being tested for multiple new targets and managing this requires precise clinical expertise. Patient recruitment is another key strategic consideration, further complicated by an increase in the number of patients needed to demonstrate that a therapy provides a significant benefit for patients.

REQUIRED STUDIES

There are occasions in which drugs behave differently in distinct situations. Three core study types are required to adequately develop a compound for market.

- **Mass Balance:** (MB) Human radiolabeled MB studies are performed to obtain information about the absorption, distribution, metabolism, and excretion of a drug in development. The main goals are to determine the route of elimination and major metabolic pathways.
- **sQTc (TQT):** Since 2005, the FDA and European regulators have required that nearly all new molecular entities be evaluated in a Thorough QT (TQT) study to determine a drug's effect on the QT interval. The TQT study serves to assess the potential arrhythmia liability of a drug.
- **Drug-Drug Interaction (DDI):** Drug-drug interactions are a common cause of adverse reactions, which can occasionally lead to serious or even fatal consequences. Understanding potential DDI through dedicated DDI clinical studies before the investigational new drug reaches Phase II and Phase III clinical trials is critical for guiding the design of these later phase trials and for identifying possible safety issues.

QPS EXPERIENCE IN ONCOLOGY TRIALS

QPS has extensive experience in supporting mass balance, QTc (TQT) and DDI studies in patient populations. We understand the complexities, particularly with respect to proper sample handling, sampling designs, bioanalysis, managing and conducting (global) clinical trials, and monitoring the activity of your new small molecule drug candidates. QPS can also conduct clinical studies in various patient populations to support your application for marketing approval. We are committed to working with you to advance your product for the benefit of patients worldwide.

QPS FOR YOUR NEXT ONCOLOGY TRIAL

Through a dedicated framework of integrated oncology research clinics and investigators, QPS offers a full range of outsourcing solutions. Whether your candidate drug is a small molecule, biologic, immunotherapy or other medication, QPS has the experience and resources to handle your drug development program and help to get your product to market. QPS provides fully integrated Phase I services, including protocol development, clinical protocol advice, clinical trial conduct, bioanalysis, and data management/ statistical analysis.

QPS ensures speedy patient recruitment through powerful associations with efficient study sites across Europe, USA and Asia, innovative patient recruitment strategies, and close links with academia, Site Management Organizations (SMOs), and specialist networks. We maintain a large worldwide database of investigators to ensure high enrollment rates of patients selected according to strict eligibility criteria. In addition, we have the capability to recruit patients in countries with a high prevalence of cancers, especially lung and breast cancers.

QPS has developed significant relationships with the investigators that conduct oncology clinical trials. These relationships provide strong foundations for ensuring quality studies are performed. We take pride in the fact that we can utilize the skills of the most experienced investigators for every clinical trial conducted by QPS.

QPS has extensive oncology experience, having conducted over 50 Phase I - IV Oncology studies across Asia, Europe and the United States. This experience covers a broad range of cancers including, but not limited to, breast, head & neck, lung, and prostate cancer. Our well-trained staff work together to produce high-quality studies, planning your clinical study from start to finish, putting in the right team and working with you to develop the best possible protocol to ensure your trial runs smoothly.

QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

BENEFIT FROM THE RESOURCES OF A GLOBAL CRO

Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of clinical trial services to support drug development needs from discovery, through clinical development and regulatory filing.

QPS

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TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT. CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!

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