

A FLEXIBLE APPROACH TO POSITRON EMISSION TOMOGRAPHY

QPS IS A GLOBAL CRO WITH DIVERSE CAPABILITIES THAT OFFERS END TO END SERVICES, INCLUDING POSITRON EMISSION TOMOGRAPHY (PET) IMAGING. PET imaging is a noninvasive study that provides quantitative spatial and functional information about molecular and cellular events.





THE PET ADVANTAGE IN NOVEL DRUG STUDIES

PET imaging offers the following advantages in the evaluation of novel drug candidates:

- ▶ It can be used as a reliable decision making tool when used in conjunction with other biomarker approaches.
- ▶ It is possible to produce positron emitting drugs that are highly target specific. Tissue kinetics and regional distribution of PET-labeled drug molecules can therefore be assessed at very low radiation doses.¹
- ▶ Repeated scanning of the same subject within a relatively short period of time is safe because of the short half-life of radioactive drugs.
- ▶ Data specificity can be further enhanced by a wide variety of selective and specific radio-tracers, such as:
 - Receptor ligands
 - Enzyme substrates and inhibitors
 - Oxygen utilization
 - Blood volume
 - Amino acids and blood flow markers

Bio-Distribution Studies

Tissue kinetics and regional drug distribution in preclinical species do not always reflect what will happen in human organ systems. This emphasizes the importance of obtaining reliable information about how a drug will affect humans during preclinical evaluation. PET imaging makes it possible to accurately assess tissue kinetics and regional drug distribution in humans.

Optimization of Drug Dosing

Early, non-invasive, human bio-distribution studies are a valuable and reliable way to evaluate drug effects on organs that are difficult to biopsy, such as the central nervous system. By using PET ligands that specifically bind to the target receptor/enzyme, important information can be obtained about:

- ▶ Occupancy of the target site at a certain drug concentration
- ▶ Time-course of occupancy
- ▶ Relative plasma and tissue kinetics of the studied drug

Characterization of Downstream Biochemical Consequences of Drug Action

For the determination of drug efficacy, measurements of downstream responses to drug action are useful. Examples of downstream response measures are:

- ▶ Glucose utilization (^{18}F -Fluorodeoxyglucose)
- ▶ Changes in cerebral blood flow (^{15}O -H $_2\text{O}$)

CHOOSING QPS FOR PET STUDIES

Choosing a partner to aid you in your novel drug investigation can be daunting. QPS provides services of the highest quality that allow your research to proceed smoothly and efficiently.

QPS delivers outstanding service in compliance with the principles of Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP).

QPS has a facility on the premises of the University Medical Center Groningen (UMCG) and maintains collaboration with the UMCG PET center. UMCG has its own cyclotron, radiochemistry laboratory and radiopharmacy, all working collectively in full compliance with GMP. This co-location facilitates a real-time collaboration that insures awareness of the latest scientific insights and technological advancements pertaining to all aspects of PET imaging.

QPS has an outstanding track record for the performance of PET studies, in particular receptor binding or occupancy studies using ^{11}C -Raclopride and ^{11}C -MDL 100907 as established radioactive drugs, but also with novel PET tracers for evaluation of radiation dosimetry, plasma pharmacokinetics, safety and tolerability and diagnostic performance in patients.²

REFERENCES:

1. FDA, Guidance for Industry and Researchers; The Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application (2010)
2. Mark E. Schmidt, Erik Mannaert, Peter de Boer, Thijs van Iersel, Antoon Willemsen, Measurement of D2 Dopamine Receptor Occupancy with ^{11}C -Raclopride PET following Single and Multiple Dose in Humans: Does Steady State Make a Difference? (2009)

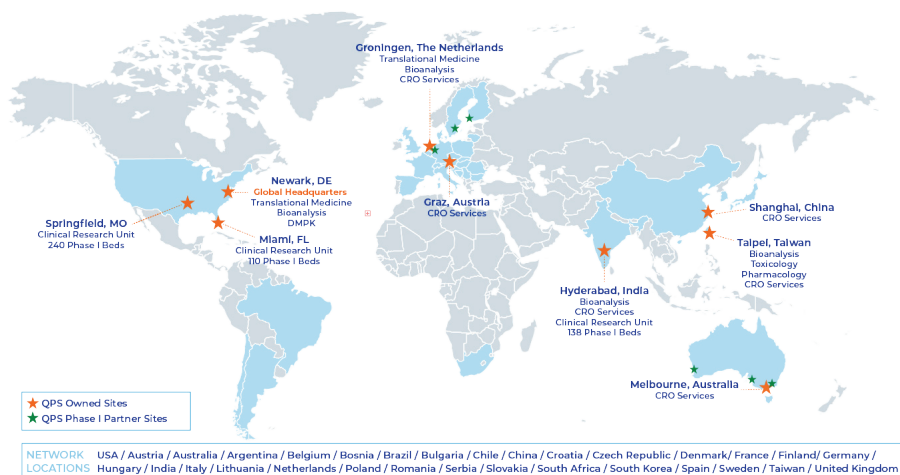


QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

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 bioanalytical services to support drug development needs from discovery, through clinical development and regulatory filing.



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**TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
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