

# QPS RARE DISEASE EXPERIENCE FULL SERVICE CRO SUPPORT

QPS is a leading full-service global CRO with extensive experience conducting research, offering comprehensive services to ensure successful drug development. Our experienced and dedicated global team provides unmatched support, from preclinical studies to bioanalysis and all phases of clinical trials.

## WHY CHOOSE QPS FOR RARE DISEASE STUDIES?

### 1. Key Strategies to Ensure Success

- ▶ Regulatory strategy embedded into execution
- ▶ Adaptive and single-arm trial expertise
- ▶ High-touch site engagement
- ▶ Global recruitment infrastructure
- ▶ Strong patient engagement

### 2. Every Patient Counts: Recruitment Strategies for Success

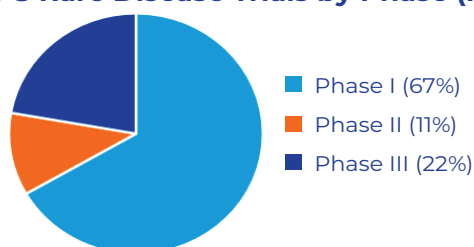
- ▶ Partner with global rare disease centers of excellence
- ▶ Activate investigator referral networks
- ▶ Focus on decentralized & hybrid trials
- ▶ Align with patient advocacy & registry partnerships

### 3. End-to-End Global Regulatory Support (FDA, EMA and Other Global Regulatory Authorities)

- ▶ Scientific advice meetings
- ▶ Pre-Submission/Pre-IND meeting requests & meeting packages
- ▶ Orphan Drug (ODD) & Rare Pediatric Disease (RPD) designation requests
- ▶ Fast Track, Breakthrough, PRIME, RMAT designation requests
- ▶ IND/CTA and NDA/BLA/MAA submissions
- ▶ Clinical trial filings
- ▶ Marketing authorization approval filings and meetings

## QPS CLINICAL EXPERIENCE IN RARE DISEASE

QPS Rare Disease Trials by Phase (N=9)



QPS Rare Disease Trials by Indication (N=9)



## CLINICAL RESEARCH OPERATIONS

- ▶ Project Management
- ▶ Patient Recruitment
- ▶ Clinical & Medical Monitoring
- ▶ Data Management & Biostatistics
- ▶ Medical Writing
- ▶ Site Selection & Feasibility
- ▶ Regulatory & Medical Affairs
- ▶ Safety & Pharmacovigilance
- ▶ Quality Assurance

## A GLOBAL SERVICE CRO

### Drug Development Services

- ▶ Pharmacology
- ▶ Toxicology
- ▶ DMPK
- ▶ Bioanalysis
- ▶ Translational Medicine
- ▶ Clinical Trial Units
- ▶ Clinical Research Services
- ▶ Clinical Trial Kits
- ▶ Central Lab Services
- ▶ PBMC and DEXA Scanning Services

### Clinical Research Services

- ▶ Project Management
- ▶ Clinical Program Management
- ▶ Clinical & Medical Monitoring
- ▶ Data Management & Biostatistics
- ▶ Medical Writing
- ▶ Quality Assurance
- ▶ Regulatory & Medical Affairs
- ▶ Safety & Pharmacovigilance
- ▶ Site Selection & Monitoring



Pharmacology



Toxicology



DMPK



Bioanalysis



Translational  
Medicine



Phase I Clinics

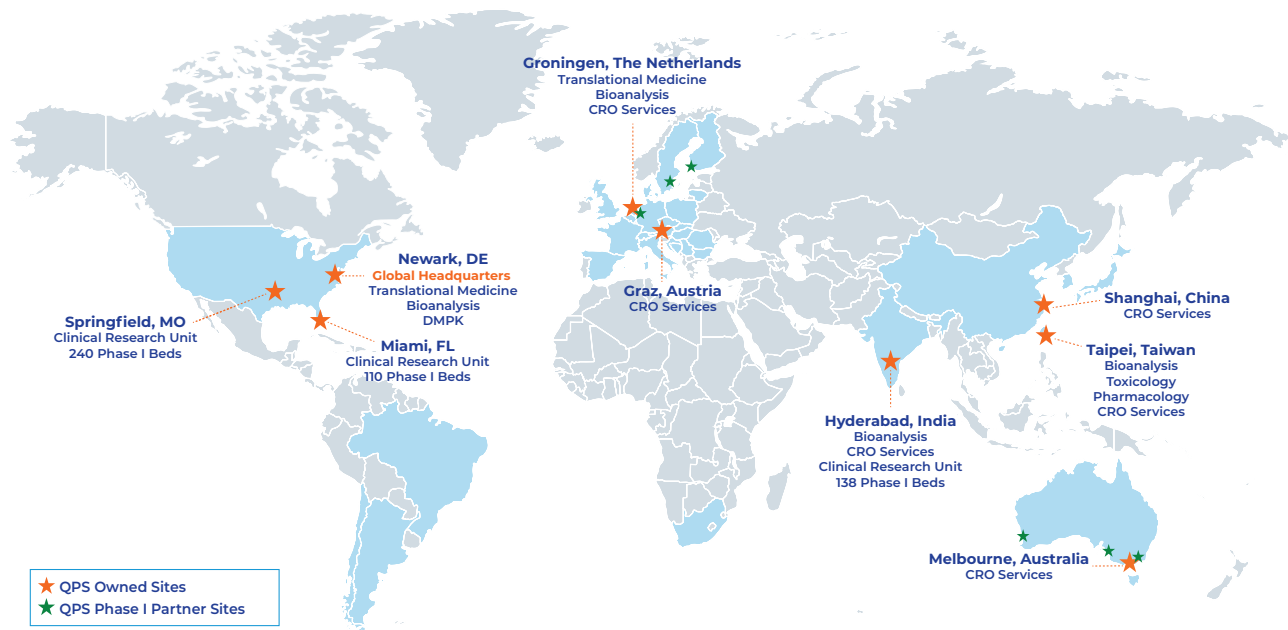


Regulatory &  
Medical



Central Lab  
Services

## QPS CLINICAL TRIAL SITES AND NETWORK LOCATIONS



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

Discover how QPS can accelerate your clinical research.

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