Quantitative Analysis
& Quality Performance
Fitting Your Passion
In Drug Development

Quantitative Analysis
& Quality Performance
Fitting Your Passion
In Drug Development

Q-fitter

**HQ** 412 Yeoksam-ro, Gangnam-gu, Seoul, South Korea 06199
**CMC Office** 222 Banpo-daero, Seocho-gu, Seoul, South Korea 06591
**Phone** 070-8676-7568 **Fax** 070-4850-8562
**E-mail** contact@qfitter.com **Website** www.qfitter.com

**Qfitter Inc.**
**Seoul, South Korea**
**Est. 2016**

# Hello,
# We are Q-fitter!

## Your life partner in drug development path!

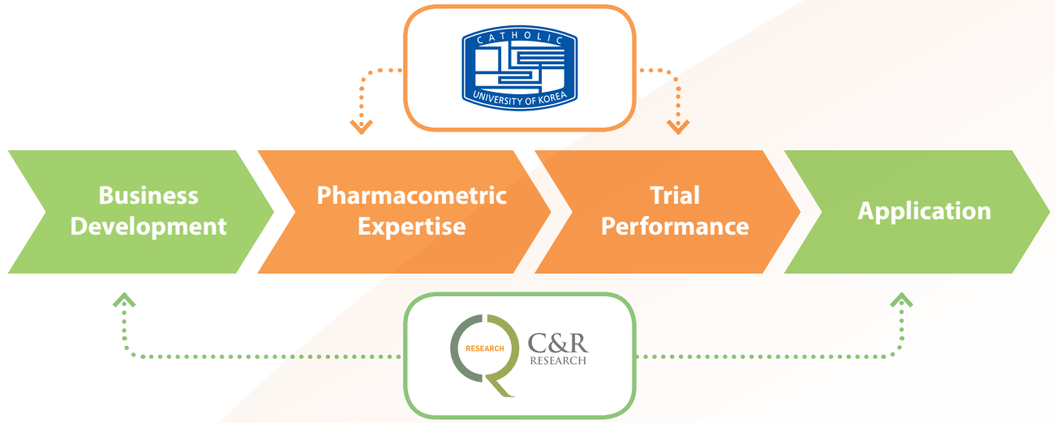
We are proud to announce the establishment of our new company, Qfitter Inc. Our professionals are dedicated to help you through the drug development process. Our job is to perform a high quality pharmacometric analysis-the use of modeling and simulation that quantifies drug, disease and trial information to support efficient drug development and regulatory decisions-and provide clinical services to support the management of early phase clinical trial.

As a collaboration platform between academia and industry, Qfitter has experiences and experts from both sides. We aim for excellence in service and we are capable of providing one. As you may know there is emerging recognition on the importance of pharmacometrics approach on trial planning by the regulatory agencies. We use this methodology to help you make assessment decisions in drug development – Is this investigational product a quick-win or fast-fail?

We want to be your One-Stop Win center in Asia located in Seoul, South Korea. We offer our services to companies of all sizes, from small to mid-size biopharmaceuticals to multinational pharmaceutical companies. We hope to be your trustworthy companion on the path to success.



# Our History




## Origin

- The Catholic University of Korea Seoul St. Mary's Hospital maintains the best clinical services in the nation in early clinical studies and pharmacometric analysis for the past 10 years. Through its continuous effort in training and education to provide better services, Pharmacometrics Institute for Practical Education and Training (PIPET), a nonprofit academic organization for pharmacometric services, was founded.
- C&R Research is the first Contract Research Organization (CRO) in South Korea established in 1997 and it has positioned itself as the number one CRO in the nation. It offers full services, including regulatory affairs, clinical trial support, medical writing, data management, and quality assurance. It continues to strive for the best services in drug development process, expanding its business to the Asia Pacific region.

## Transition

- As Korea's new drug development market emerges, more effective and updated procedures in drug development process are in demand. Sponsors asked for validated pharmacometric analysis and clinical trial sites with higher level of services capable of producing reliable data. Purchasable services with high quality beyond the academic level were sought after. With evolving market needs, PIPET pursued to transition itself to a practical business model in the market. C&R Research looked for a partner to enhance the quality of performances in drug development services and bring status quo of CRO to its next-generation of business. A Highly specialized new business model was required to independently provide services to complement needs from both sides, and to fill a niche in the market.

## Collaboration

- At last, an academia-industry collaboration platform, Qfitter, Inc. was established, providing marketable services in pharmacometrics and clinical pharmacology to clients combining rich experiences of academia and management system of the Industry. Through the recruitment of our top-tier researchers in the field and defining our roles and responsibilities, the collaboration came to fruition and is fully operating to guide your drug pipeline in the right direction.

# Goals

Quantify the evidence to improve productivity

Provide quality services to improve efficiency

Provide innovative treatment & Make positive changes in drug development and approval

Benefit health and wellness of people

# Core Values


**Collaboration** Synergy through Academia-Industry partnership with high quality performance

**Integration** Integrative services in pharmacometric analysis and clinical trials for faster and smarter process

**Value-Maximization** Add value to your investigational product with customized services and enhanced communication



# Vision

True companion in Drug Development with Dedicated Experts

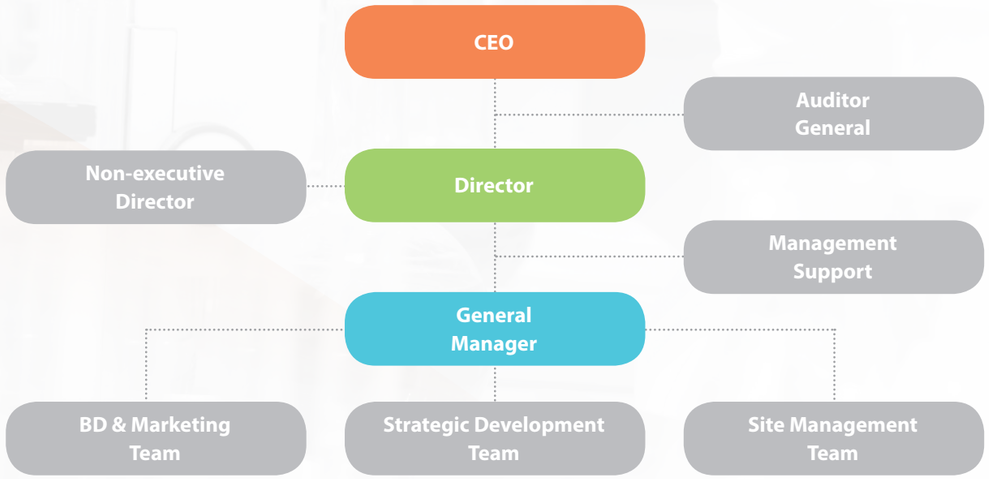
One-Stop Quick-Win Center in Korea

Reliable Partner in Decision-making for Drug Development

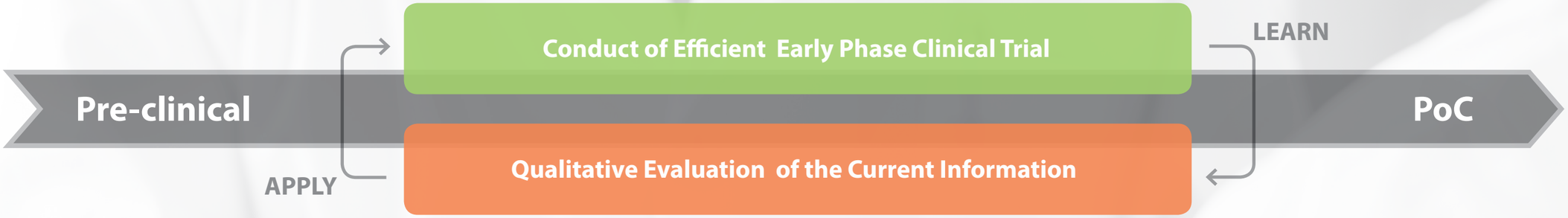
Driver to Overseas Regulatory Submission

# Organization

Our Strategic Development Team performs modeling and simulation on nonclinical and clinical study data. Site Management Team supports clinical operation in early phase clinical trials and Business Development & Marketing Team facilitates contractual work and forwards new opportunities. Non-executive directors from the Catholic University of Korea Seoul St. Mary's Hospital bring our corporate partner, Pharmacometrics Institute for Practical Education and Training (PIPET), to enrich our clinical experiences and database. As our parent organization, we have C&R Research to complement our management.



# Our Services




## Conduct of Efficient Early Phase Clinical Trial

We provide a full range of services on early phase clinical trials in healthy volunteers. Qfitter's top-notch investigator and clinical research coordinator (CRC) are delegated to provide operational management services. Along with the supportive services, advisory services from a clinical pharmacology perspectives, including designing and revising a protocol, are offered. Our scientific writing includes but is not limited to protocols, Case Report Forms (CRF), Informed Consent Forms (ICF) and Clinical Study Reports (CSR).

- Early-phase trial designing
- Protocol development
- Trial-related document development (CRF, ICF, various forms, etc.)
- Patient-based early-phase trial research team construction
- New therapeutics regulatory affairs (Cell therapy, Gene therapy, etc.)
- Clinical trial participation as an investigator
- CRF fill-up + Quality Control (QC) /Quality Assurance (QA) activities
- Statistical analysis and CSR writing

### Types of Studies Conducted

- First-Time-in-Humans (FTIH)
  - Micro-dosing studies (Phase 0)
  - Single Ascending Dose (SAD)
- Multiple Ascending Dose (MAD)
- Bioavailability / Bioequivalence (BA/BE)
  - Formulation comparison
  - Combination formulations
- Food Effect studies (FE)
- Drug-Drug Interaction studies (DDI)
- Thorough QT studies (TQT)
- Therapeutic exploratory studies (Phase IIA)

### Therapeutic Areas of Expertise

- Cardiology
- Endocrinology & Metabolism
- Hematology
- Infectious Diseases
- Immunology
- Neurology
- Oncology
- Rheumatology
- Urology
- Vaccines
- Natural Products

## Qualitative Evaluation of the Current Information

Our projects are often initiated via in-person discussion followed by confidentiality documents. Following the delivery of quotation outlining estimated timeline and project cost, a contract is made upon mutual agreement. Data set is received via exchange of internet electronic files. Preliminary analysis is done and regular in-house meetings with sponsors follow on an as-needed basis. International consultation is also available via telecommunication or email.

- Population PK/PD analysis
- Nonclinical PK/PD modeling & simulation
- First-in-Human (FIH) dose estimation based on nonclinical PK/PD modeling
- Human PK/PD evaluation via early clinical trial data
- Non-Compartmental Analysis (NCA) on early clinical trial data
- Drug development consultation on clinical study design
- Pharmacometric consultation: Liaison services with bioanalytical facilities and sponsors to ensure PK data integrity and to provide data interpretation
- Scientific report writing

### Questions We Can Answer

- What data is required to perform quantitative PK/PD analysis? (Non-clinical / Clinical)
- What are the optimal timepoints to acquire PK/PD data? (Non-clinical / Clinical)
- What is the most recommended FIH starting dose and dose-escalation scheme?
- Is the candidate predicted to be efficacious in human, and if so, in what dose level?
- What is the best development strategies for the candidate in terms of PoC?
- What is the recommended clinical trial design to ensure efficiency in drug development?

### Experiences (2014~)

| Indication | Stage | Purpose |
|---|---|---|
| Anti-cancer (cytotoxic) | Non-clinical | Evaluation of anti-tumor effect |
| Anti-cancer (target) | Non-clinical | Human starting dose estimation |
| Anti-hepatitis (mAb) | Clinical | Estimation of clinically-applicable dose |
| Dislipidemia | Non-clinical | Human starting dose estimation<br>First-in-human trial design |
| Dislipidemia | Clinical | MAD design |
| Dislipidemia | Clinical | Prediction of Food Effect |
| Inflammatory Disease | Non-clinical | First-in-human trial design |
| Autoimmune (mAb) | Clinical | Evaluation of PK similarity to comparator drug |
| Infectious Disease (mAb) | Clinical | Population PK analysis |
| Infectious Disease | Clinical | Phase II trial design |
| Peptic ulcer | Clinical | Multiple dose PK prediction |
| Autoimmune (mAb) | Clinical | Phase II trial design |
| Anti-cancer (target) | Non-clinical | First-in-human trial design |
| Anti-cancer | Clinical | Phase II trial design |