Clinical Pharmacodynamics

We apply our experience and expertise to expedite our Sponsor's early clinical trials.

The main focus in Phase I clinical trials has traditionally been assessment of safety and tolerability. However, in recent years there is increasing interest in the application of biomarkers and surrogate endpoints in healthy volunteer studies. These studies provide pivotal information on efficacy, dose-response and time-effects of drugs.

The pharmaceutical industry itself has a growing pressure to develop medicines more quickly and cost-effectively with early read-outs on putative efficacy or potential development obstacles obtained. Our cutting edge pharmacodynamic models can provide this for you.

Innovation in Clinical Pharmacodynamics

The dedicated Clinical Pharmacodynamics group at ICON has developed and validated a variety of pharmacodynamic models for a range of clinical conditions including:

Acute Pain

Diabetes

Audiometry

Physiological Measurements

- Temperature
  - Infra-Red Skin Temperature
  - pH Monitoring
- Peripheral
  - Skin Conductance Measurement

Cognitive Testing

- Computerised
  - Word Recall Test
  - Collaborations with major suppliers including CogState

Rating Scales

- Bond and Lader Scale
- General Health Questionnaire
- Symptoms Checklist
- Sleep Questionnaires
- Leeds Sleep Evaluation Questionnaire
- Karolinska Sleepiness Scale

Clinical Pharmacodynamic Service Offerings

Pharmacodynamic Models / Specialist Techniques

Pain Models

– Acute Pain
  - Cold Pain Test

– Chronic Pain Models
  - Pain VAS, Topical Capsaicin Model, Mustard Oil Model

Pupillometry

– Static/Dynamic Measurements

– Crossed-pupillary Response Respiratory

Respiratory

– Peak Flow Rate

– Flow Loops

Electroencephalography

– Clinical EEG

– Evoked Potential

Full Service Early Phase Development

ICON's Early Phase Development team specialises in the strategy and delivery of early drug development, with multidisciplinary expertise from compound selection through to proof-of-concept clinical development. ICON successfully delivers results for informed, timely decision making.

ICON offers expertise in non-clinical development, early-phase clinical research, bioanalytical, PK, PD modelling & simulation and regulatory affairs together with the full range of support services.

Validated Models

Validated models enable the investigation of how compounds can modulate the elicited symptoms. In healthy volunteers, they offer a rapid and cost-effective method of determining if a molecule is worth taking further forward in the development process. In the case of a number of potential compounds existing in a pipeline, they can provide an additional means of ensuring that the best candidate is selected for development.

PK/PD Modelling & Simulation

ICON's Early Phase Development team has industry-recognised expertise in the application of pharmacokinetic (PK) and pharmacodynamic (PD) principles critical for successful drug approval, with experience over the past 5 years that includes the following:

– Over 300 PK projects

– 80 population PK and PK/PD analysis and reports

– Vast experience in interactions with regulatory authorities on PK and biopharmaceutics results, leveraging staff member regulatory career experience and regular interactions on behalf of clients

Developing PK/Biopharmaceutics Strategy as Part of the Drug Development

ICON applies its scientific and regulatory expertise to developing over-arching PK/PD strategy — designing individual PK studies and substudies to expedite the drug development process.

For more information, please contact:

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