Excellence in Clinical Pharmacodynamics

We work to find a better way. 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 in assessment of safety and tolerability. However, in recent years there has been increasing interest in the application of biomarkers and surrogate end points in healthy volunteer studies to provide pivotal information on efficacy, dose-response and time-effects of drugs.

There is a growing pressure within the pharmaceutical industry to develop medicines as quickly and cost-effectively as possible. Early read-outs on putative efficacy or potential obstacles can be hugely beneficial in achieving this. Our cutting edge pharmacodynamic models can provide this for you.

Innovation in Clinical Pharmacodynamics
The dedicated Clinical Pharmacodynamics group at ICON Development Solutions has developed and validated a variety of pharmacodynamic models in a broad range of therapeutic areas including:

- Pain
- Inflammation
- Appetite/Obesity
- Anxiety
- Cognitive Function
- Metabolic Function/Diabetes
- Sexual Dysfunction

www.iconplc.com
Pharmacodynamic Models

**PAIN**

- Acute Pain
  - Cold Pain Test
  - Heat Pain Detection Threshold
  - Heat Pain Tolerance Threshold
  - Brief Thermal Stimulation

- Chronic Pain
  - Intradermal Capsaicin Model
    - Hyperalgesia
    - Allodynia
    - Pain VAS
    - Flare Assessment
  - Topical Capsaicin Model
  - Mustard Oil Model
  - Heat-Capsaicin Model
  - Electrical Hyperalgesia Model
  - Menthol Cold Allodynia Model

**APPETITE / OBESITY**

- Test Meal Model
  - Universal Eating Monitor
  - Validated Questionnaire
  - Bioelectrical Impedance
  - Food Diaries

**ANXIETY**

- Simulated Public Speaking Model
- Aversive Conditioning Model
- CO$_2$-Induced Anxiety

**COGNITIVE FUNCTION**

- Scopolamine Model

**SEXUAL DYSFUNCTION**

- Ejaculatory Latency Model

**METABOLIC FUNCTION / DIABETES**

- Glucose Clamp
Specialist Techniques

ACTIGRAPHY

AUDIOMETRY

COGNITIVE TESTING
Computerised
- In-House Mobile Phone-Based System:
  - Choice Reaction Time
  - Number Pairs
  - Continuous Attention
  - Information Processing
  - Digit Vigilance
  - Serial Sevens
  - Bond & Lader
- Word Recall Test
- Collaborations With Other Major Vendors:
  - CogState
  - Cantab

Pencil And Paper
- Trail Making
- Verbal Fluency
- Digit Symbol Substitution
- Stroop Test
- Gibson Spiral Maze
- Memory Tests (List, Design, Story Recall)
- Bushke Selective Reminding Task

ELECTROENCEPHALOGRAPHY
- Clinical EEG
- Pharmaco-EEG
- Evoked Potentials

IMAGING
- Laser Doppler Flowmetry
- Formal Collaborations with Local PET and fMRI Centres

MEASURES OF SEDATION
- Saccadic Eye Movements
- Postural Stability
- Critical Flicker Fusion

PHYSIOLOGICAL MEASUREMENTS
- Temperature Monitoring
  - Continuous Core Body Temperature (Ingestible Capsule)
  - Continuous Skin Temperature (Dermal Patch)
  - Infra-Red Skin Temperature
- GI pH Monitoring
  - Continuous Monitoring (Bravo Capsule)
  - Endoscopic Monitoring and Drug Release Techniques
- Peripheral
  - Skin Conductance Assessment

PUPILLOMETRY
- Static/Dynamic Measurements
- Crossed Pupillary Response

QUANTITATIVE SENSORY TESTING (QST)
- Perception Thresholds
- Heat Detection
- Cold Detection
- Wind Up Ratio
- Mechanical Pain Threshold/Sensitivity
- Pressure Pain Threshold

RATING SCALES
- Bond & Lader
- Profile of Mood State
- Bastani Scale
- Spielberger Anxiety (State/Trait)
- General Health Questionnaire
- Symptoms Checklist
- Bodily Symptoms Scale
- Eysenck Personality Scale
- ARCI-49
- Sleep Questionnaires
  - Leeds Sleep Evaluation
  - Karolinska Sleepiness Scale

RESPIRATORY FUNCTION
- Basic Spirometry (FEV, FVC)
- Flow Loops
ICON Development Solutions, a division of ICON plc, specialises in the strategy and delivery of early drug development, with multidisciplinary expertise from compound selection through to proof-of-concept clinical development. ICON Development Solutions successfully delivers results for informed, timely decision making.

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

**History of Excellence**
The clinical pharmacodynamics group provides specialist support to studies in the clinical unit, as well as offering a range of validated models and techniques.

With over 15 years of experience in clinical pharmacodynamics, our skilled team of scientists can give you the cutting edge you need.

**Pharmacodynamic Models**
Validated pharmacodynamic models allow the effect of an investigational compound to be determined on symptoms induced under controlled conditions. In healthy subjects they offer a rapid and cost-effective method of assessing the effects of a molecule and in determining its future potential. They can also provide an additional means of ensuring that the best candidate is selected for development in situations where multiple compounds exist in a pipeline.

For more information, please contact: IDSinfo@iconplc.com