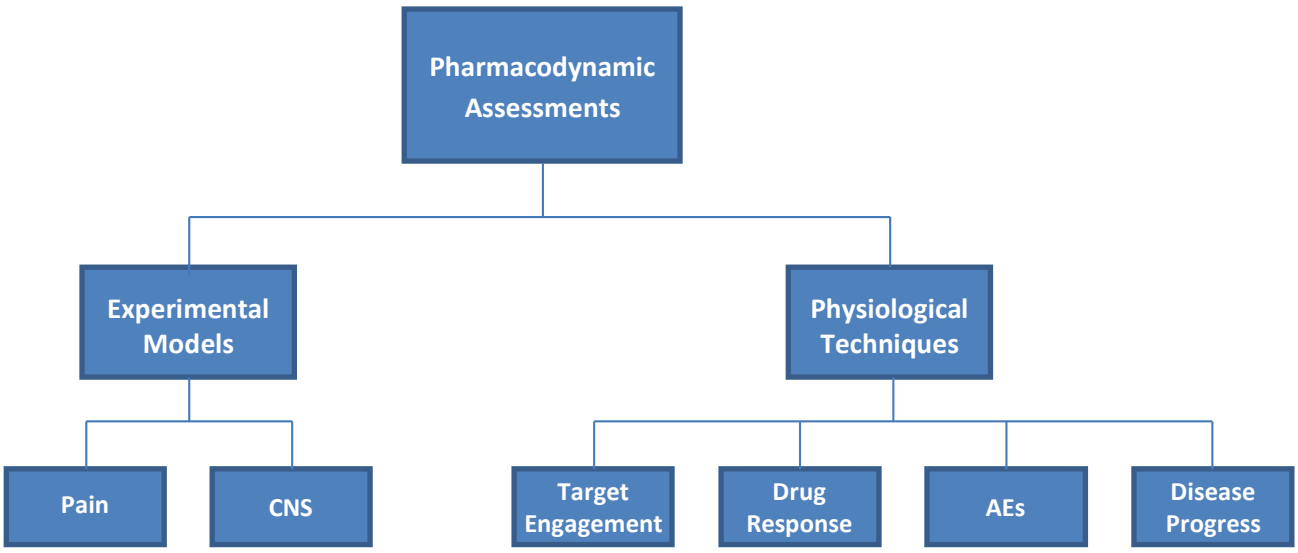
CLINICAL PHARMACODYNAMICS

The application of pharmacodynamic assessments in both healthy volunteers and patients can be hugely beneficial as part of the early drug development process. The use of experimental models, where symptoms of a particular disease state are induced under controlled conditions, allow putative efficacy of compounds to be investigated in a "clean" manner. In addition to models, a whole range of pharmacodynamic techniques can be utilised to help paint a clearer picture about the activity of a drug.

In recent years there has been a clear shift in focus in early phase clinical research towards trying to leverage increased information at this stage of the development process. As well as the traditional objectives of safety and tolerability, there is now an increased interest in using Phase 1 trials to provide pivotal information about potential efficacy, as well as increasing understanding of dose response and the time course of effects. This additional information can prove to be both valuable and cost effective; cutting down on the scope of costly patient trials and providing increased confidence moving forward with future development from both a scientific and financial perspective.

Pharmacodynamic Assessments

- Experience in a wide range of pharmacodynamic assessments
  - Human experimental models to test potential efficacy
  - Physiological techniques to determine pharmacodynamic drug effects
- Can be administered as part of Phase 1 SAD/MAD trials, Phase 2/3 patient trials or in stand-alone PD studies
- Can be applied in HV or patients
- Highly trained, experienced testers ensure consistency and reproducibility



Pharmacodynamic Assessments at MAC Clinical Research

Models		
Pain	Inflammation	Cognition
Cold Pain Test	Cantharidin Blister Model	Scopolamine Model
Thermal Stimulation	Tape Stripping	
ID/Topical Capsaicin	UVB Model	
Electrical Stimulation	Histamine Wheal & Flare	
Techniques		
Pain	General	
Quantitative Sensory Testing - Thermal Thresholds/Tolerance - Pressure Pain Threshold/Tolerance - Stimulus induced pain - Pain Matching - Hyperalgesia / Allodynia	Subjective Rating Scales Cognitive Testing - Neuropsychological Assessment - Psychometric Assessment Saccadic Eye Movements Pupillometry Postural Stability	Imaging (fMRI, PET, MRS) Actigraphy Respiratory Function Testing Exercise Testing Punch Biopsy Bleeding Time Platelet Aggregometry
Focused Analgesia Selection Test		
Nerve Conduction		

Scientists at MAC Clinical Research have extensive experience in the set-up, validation and application of a wide range of PD assessments. The table above details some of the most widely used models and techniques, however we are able to offer assessments in other therapeutic areas, including anxiety and appetite control, if required.

Excellent collaborative links with local imaging centres allow us access to state of the art imaging techniques which can be combined with PD assessments to provide in depth information about the progression of disease or the activity of a compound.

These factors, coupled with an extensive patient database and experience in recruiting a wide range of patient populations in the pain and CNS areas, mean that we are well placed to meet your pharmacodynamic study requirements in both patients and healthy volunteers.

If you would like any further information about any of our pharmacodynamic assessments or our general capabilities please contact:

pharmacodynamics@macplc.com

Or visit our website at:

www.macplc.com

MAC Clinical Research