

PharmaForum

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1. Company

daacro

*diagnostic assessment and
clinical research organization*

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daacro is a contract research organization performing phase I and IV clinical trials for pharmaceutical companies and clinical studies for the healthcare and nutritional supplement industries.

daacro was founded in 2003 by scientists as a spin-off at the University of Trier to routinely meet the extensive legal requirements for clinical research. An efficient and reliable administrative team organizes a multidisciplinary team of experts in basic research, clinical and CRO activities. Daacro's prominent scientific advisory board adds additional expertise. The company is based in Trier, Germany and carries out studies in many different locations.

daacro's particular expertise lies in the advanced assessment of the effects of psychotropic substances on anxiety, depression and stress.

2. Core competence

**A New Pharmacodynamic Tool for Clinical Trials:
TSST – the Trier Social Stress Test**

The TSST was developed 18 years ago at the University of Trier. Since then, thousands of probands and patients have been tested. Today, the TSST is viewed as the most reliable, valid and best standardized laboratory protocol for the assessment of social stress and anxiety in humans (see Dickerson & Kemeny, 2004).

Based on many years of development and experience, daacro provides the highest standard and expertise in applying this protocol in clinical research. Daacro was the first CRO to demonstrate high sensitivity of the TSST to the effects of anxiolytic drugs (see Fries & Hellhammer & Hellhammer, 2006) and thereafter, integrated it as a pharmacodynamic element in phase I clinical trials.

www.daacro.com

A New Module System for the TSST-Protocol:

Depending on the compound and the target, different measuring instruments are available to be added to the study protocol:



Module I – Autonomic Response Measures

- + blood pressure, epinephrine, norepinephrine
- + electrocardiogram, heart rate variability
- + electrodermal activity, perspiration
- + body temperature
- + pupilography

Module II - Endocrinological Response Measures

- + ACTH, serum and salivary cortisol
- + prolactin, growth hormone, DHEA

Module III – Immunological Response Measures

- + leukocyte subsets
- + cytokines

Module IV – Hematological Response Measures

- + hematocrit, hemoglobin

Module V – Metabolic Response Measures

- + hemoconcentration (hematocrit, hemoglobin, plasma volume)
- + blood coagulation (fibrinogen, von Willebrand factor antigen, D-dimer, clotting factors)

Module VI – Gene Expression

- + repression, induction profiles of genes in target tissues

Module VII – Psychomotor Response Measures

- + electromyogram
- + voice (spectral analyses)
- + limb movements
- + dexterity

Module VIII – Psychological Response Measures

- + state anxiety
- + mood, anger, fear, helplessness
- + coping
- + memory, attention

All these modules are proven and have been tested in the TSST.

A New Diagnostic Tool for Stress Related Disorders: neuropattern™

A new diagnostic system based on the most recent neurobiological research has been developed to improve treatment of stress-related health disorders. Chronic stress can provoke numerous dysfunctions of the brain and the body. However, the mechanisms behind these dysfunctions are intra-individually complex and inter-individually heterogeneous. Our new diagnosis system enables us to differentiate such functional changes within the individual for the first time. Each dysfunction can be characterised by a specific pattern of biological, psychological and symptomatic events. Currently, the system is able to assess 15 different patterns (Neuropatterns).

3. Cooperations offered

We offer:

a. CRO Services and Performance of Clinical Trials with Scientific Competence in Basic and Clinical Research

We routinely apply the TSST in clinical trials and other studies. From protocol design, study preparation, performing trials, data analysis, preparing study reports and publications, and hosting scientific meetings and training, we offer the whole spectrum of a CRO.

b. neuropattern™ - Stress Diagnostics

This innovative and newly developed tool identifies neuroendophenotypes, which are associated with stress pathology. It can be used for both case studies in single patients and larger epidemiologic or clinical studies.

The basic concept has recently been published in “Stress. The Brain-Body Connection.” Eds. Hellhammer, D. & Hellhammer, J. 2008, Karger.

c. Saliva Testing Laboratory Services

In cooperation with Salimetrics, USA daacro offers innovative salivary immunoassay products and provides testing services to aid researchers, the immunodiagnostic industry and analytical and functional testing laboratories around the world in measuring stress biomarkers, including: Alpha amylase, Androstenedione, Blood contamination, Cortisol, C-reactive protein, DHEA, Estradiol, Progesterone, 17a-hydroxyprogesterone, Secretory IgA and Testosterone.

d. Services in Questionnaire Development and Biostatistics

daacro has an interdisciplinary and international research network and seeks further partnership in research and development cooperation.