



NEWS

OTC power // Beyond the counter // The daacro clinical trial volunteer report // Slimming study // Cuddle hormone oxytocin

Dear Readers,

During our years of experience as a CRO, we have confirmed time and time again how important our advice is for companies throughout the entire product development process. In particular, when developing new products in the self-medication and consumer healthcare sectors, the development and marketing concepts must be in tune with one another. A complete and holistic approach should similarly include regulatory frameworks, scientific expertise and innovative, market-oriented strategies. In order to better meet these demands, we have founded Orange OTC in collaboration with excellent partners. This interdisciplinary group of experts manages the development and marketing of OTC products with a skilful and integrated approach.

daacro's focus within this group of experts lies in scientific expertise in clinical research and highly customised planning of studies for our clients. This is how we contribute towards improving early (medical) interventions in common diseases.



Juliane Hellhammer
Founder & CEO of daacro



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SAVE THE DATE

VITAFOODS
05 - 07 MAY 2015
GENEVA, SWITZERLAND

ASSOCIATION OF THE EUROPEAN SELF-MEDICATION INDUSTRY AESGP
26 - 28 MAY 2015
BARCELONA, SPAIN

NUTRITION INTEGRATES
04 JUNE 2015
LONDON, UK

INTERNATIONAL COLLEGE OF NEUROPSYCHOPHARMACOLOGY THEMATIC MEETING
Stress, Inflammation, and Depression: focus on novel psychotropic drug targets
04 - 06 JUNE 2015
DUBLIN, IRELAND

INTERNATIONAL SOCIETY FOR PSYCHO-NEUROENDOCRINOLOGY ISPNE
Stress and the Brain: from Fertility to Senility
08 - 11 SEPTEMBER 2015
EDINBURGH, UK

FOOD MATTERS LIVE
17 - 19 NOVEMBER 2015
LONDON, UK

FOOD INGREDIENTS
01 - 03 DECEMBER 2015
PARIS, FRANCE

1 GOOD DATA RELIES ON GOOD INSTRUMENTS



Stress belt for stress measurement
Picture Credits: movisens GmbH



Heart rate and heart rate variability are biomarkers for the activity of the autonomic nervous system and, as a result, are important information in many clinical studies. Simple management is advantageous; having reliable data, however is essential. We tested Movisens' stress belt developed by a team of experts led by Dr. Stefan Hey at the University of Karlsruhe.

The stress belt contains ekgMove, a psychophysiological, ambulant measurement system that records ECG, temperature and atmospheric pressure. Target parameters such as heart rate, heart rate variability, activity classes and energy use are calculated using Movisens' DataAnalyser software and presented as reports in pdf files. The sensor is attached to a flexible chest band. The edaMove can also measure electrodermal activity (EDA), also known as galvanic skin response (GSR). EDA is very sensitive to stress factors, which is why EDA is an important target parameter for physiological reactions to stress.

We tested the system in comparison with a well-established system in a sporting situation and in a laboratory stress test, the Trier Social Stress Test. The Movisens' system is easy to manage, has an appealing design and delivers data that are easy to compare. The manufacturer has indicated that it will have received authorisation as a medical device by the end of 2015. Therefore, the stress belt is conceivably a good alternative for use in clinical studies.



2 OTC POWER

A NEW PROVIDER OF CLINICAL STUDIES AND STRATEGIC ADVICE HAS ENTERED THE MARKET TO REVOLUTIONISE NON-PRESCRIPTION MEDICINES AND RELATED PRODUCTS.

For the first time, an alliance with Orange OTC Research has been launched specially for consumer healthcare in Europe.

Behind Orange OTC Research are industry experts including Juliane Hellhammer from the contract research organisation daacro GmbH & Co. KG, Dr. Stefan Sandner from the pharmaceutical service provider Diapharm GmbH & Co. KG and Dr. Burkhard Breuer as well as Dr. Marion Breuer from the contract research organisation proinnovera GmbH. As CROs and consultants, these partners pool their specialist knowledge within this joint venture to counteract the trend of flattening OTC product profiles. The aim is to create new opportunities for market presence using creative study designs and modern technologies for consumer healthcare products. Juliane Hellhammer explains, "Our OTC studies are established on a scientific medical basis but also contribute study designs that are adapted to the products' special market requirements. This is considerable added value in comparison to traditional marketing studies."

AN INNOVATION FOR THE CONSUMER HEALTHCARE SECTOR

The strategic approach and the specialisation as a consumer healthcare CRO for prescription-free medicines and related health products such

as "nutraceuticals" and "cosmeceuticals" is a completely new concept in Europe. As a result, Orange OTC Research has taken a pioneering role in detrialising consumer healthcare products. Dr. Stefan Sandner emphasises the point: "By combining sound market knowledge, regulatory OTC expertise and custom-focused studies, we are now giving manufacturers the option of repositioning their products and brands off the beaten path – thanks to innovative and medical regulatory safeguarded claims."

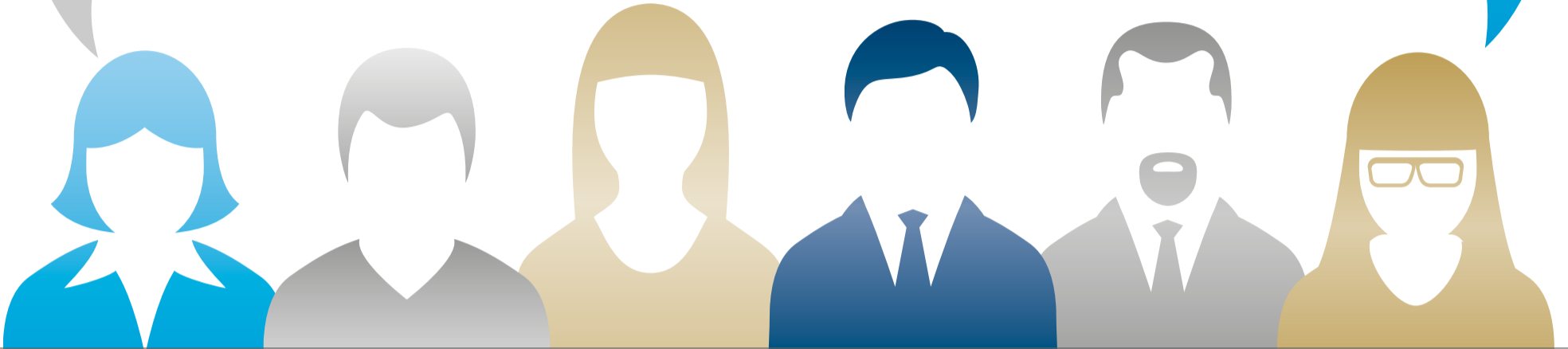
BACKGROUND INFORMATION:

Orange OTC Research is a cooperation between three specialist service providers with decades of experience in the consumer healthcare and pharmaceutical industries. Diapharm GmbH & CO. KG (www.diapharm.com), with its headquarters in Münster, has been operating as a service provider and consulting company for the consumer healthcare and pharmaceutical sectors since 1988. Founded in 1997 in Münster as a full service CRO, proinnovera GmbH (www.proinnovera-cro.de) undertakes all services involved in clinical studies and regulatory demands, both on national and international levels. Daacro GmbH & Co. KG (www.daacro.com), the contract research organisation based in Trier, has been designing study concepts and designs focused on CNS since 2003, carrying out clinical studies and evaluations and, upon request, also writing the corresponding academic publications.

“INTERESTING STUDY, VERY NICE PEOPLE, I FELT I WAS IN GOOD HANDS.”

“ALWAYS KINDLY LOOKED AFTER AT APPOINTMENTS. DETAILED INFORMATION ABOUT THE STUDY AND ALWAYS SATISFYING ANSWERS TO QUESTIONS THAT AROSE. ALSO, VERY FLEXIBLE WITH ARRANGING AND CHANGING APPOINTMENTS.”

“VERY KIND AND SKILFUL STAFF. INTERESTING STUDY EXPLAINED WITH LOTS OF MOTIVATION.”



3 SATISFACTION IN NUMBERS: THE DAACRO CLINICAL TRIAL VOLUNTEER REPORT

A WELL-DEFINED STUDY POPULATION, WITH AN AS OPTIMAL A FIT AS POSSIBLE FOR THE QUESTION DEFINED IN THE STUDY DESIGN, IS ESSENTIAL FOR A STUDY'S OUTCOME.

We constantly recruit participants for our studies through traditional advertising channels and publicity campaigns. Our website werdproband.de, aimed specifically at recruitment, informs potential volunteers about our latest studies and gives them the option to register as a volunteer in our volunteer database. It now holds over 2 500 relevant datasets and is growing daily.

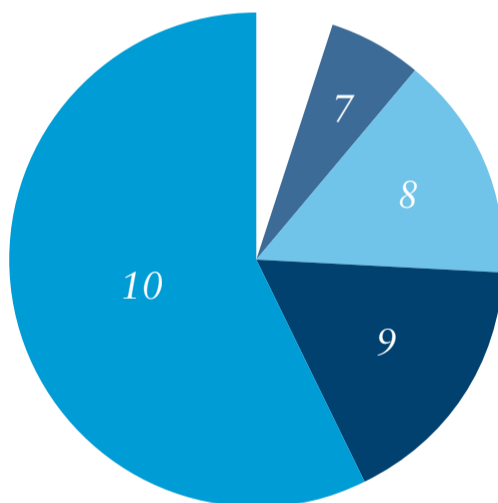
FIT FOR PURPOSE

The relevance/precision of the collected personal data allows us to quickly recruit suitable participants for the studies (i.e. participants that are fit for purpose). If studies are planned for particular groups of patients, we also take advantage of our excellent local and cross-regional networks of practising (specialist) doctors and clinics.

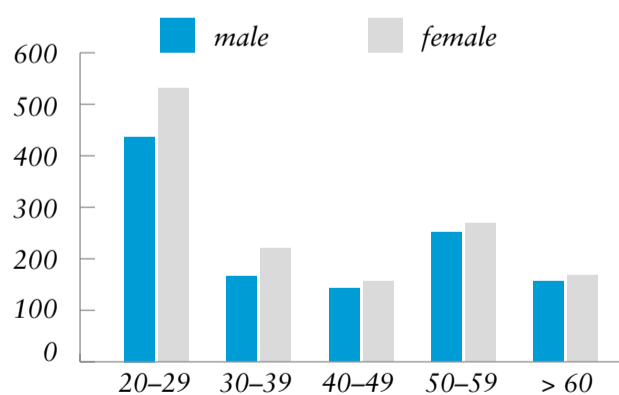
From May 2013 to February 2015, we asked our volunteers how likely is it that they would recommend participating in a clinical study with daacro to a friend or colleague. Our volunteers were given a scale of 1 to 10 to rate the likelihood of an onward recommendation, whereby 1 stood for completely unlikely and 10 for very likely.

The answers speak for themselves. 58% of our volunteers would recommend us on to others without hesitation and a further 32% awarded us 7, 8 or 9 points.

Likelihood of onward recommendations



Current mix of volunteers according to age and gender



OUR CLINICAL TRIAL VOLUNTEERS HAVE PARTICULARLY PRAISED THE KIND AND SKILFUL CARE THEY HAVE RECEIVED FROM THE DAACRO TEAM.



NEW IN THE DAACRO TEAM

Dr. Michael Clemens' team has acquired new reinforcements. The new study managers in the daacro team are:



**Anna Roeltgen,
Study Manager**

Bachelor of Science in Psychology from the University of Trier
Further key areas:
Recruiting, scientific literature database



**Nicole Weber,
Study Manager**

Degree in Psychology from the University of Trier
Further key areas:
Bio-psychology, study protocol development

4 SLIMMING STUDY



DAACRO CARRIES OUT STUDIES IN WEIGHT LOSS IN JUST FOUR WEEKS – IN TWO DOUBLE-BLIND, PLACEBO-CONTROLLED AND RANDOMISED STUDIES.

In the two double-blind, placebo-controlled and randomised studies, 180 men and women were examined using a combined product (glucomannan, on the EFSA claims positive list, combined with the services of a nutrition consultant). In the first study, the intake period accounted for four weeks, in the second for eight weeks. The results were submitted to the sponsor as early as December 2014 and January 2015 due to our rapid completion and evaluation of the study.

LATEST PUBLICATIONS

Hellhammer, J., Vogt, D., Franz, N., Freitas, U. & Rutenberg, D. (2014). *The soy-based phosphatidylserine/phosphatidic acid complex MemreePlus normalizes the stress reactivity of hypothalamus-pituitary-adrenal-axis in chronically stressed male subjects: A randomized, placebo-controlled study.* *Lipids in Health and Disease*, 13-121

Biehle-Huette, S. J., Krailler, J. M., Elstun, L. T., Bentz, S., Benzing, K. W., Spruell, R. D., Hellhammer, J. & Swaile, D.F. (2014). *Thermoregulatory vs. event sweating – comparison of clinical methodologies, physiology and results.* *International Journal of Cosmetic Science*, 36: 102–108

Hot off the press: *The Trusted Clinical Trials Business Resource.* *Applied Clinical Trials.* www.appliedclinicaltrialsonline.com/new-german-based-cro-enters-otc-sector

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iStock Photo, movisens GmbH, Hans Werner Bohn

5 CUDDLE HORMONE OXYTOCIN HELPS ALLEVIATE STRESS

MEASURING OXYTOCIN IN SALIVA:

DAACRO'S SALIVA LAB COOPERATES TO EXPAND ITS SPECTRUM OF HORMONE MEASUREMENTS IN SALIVA

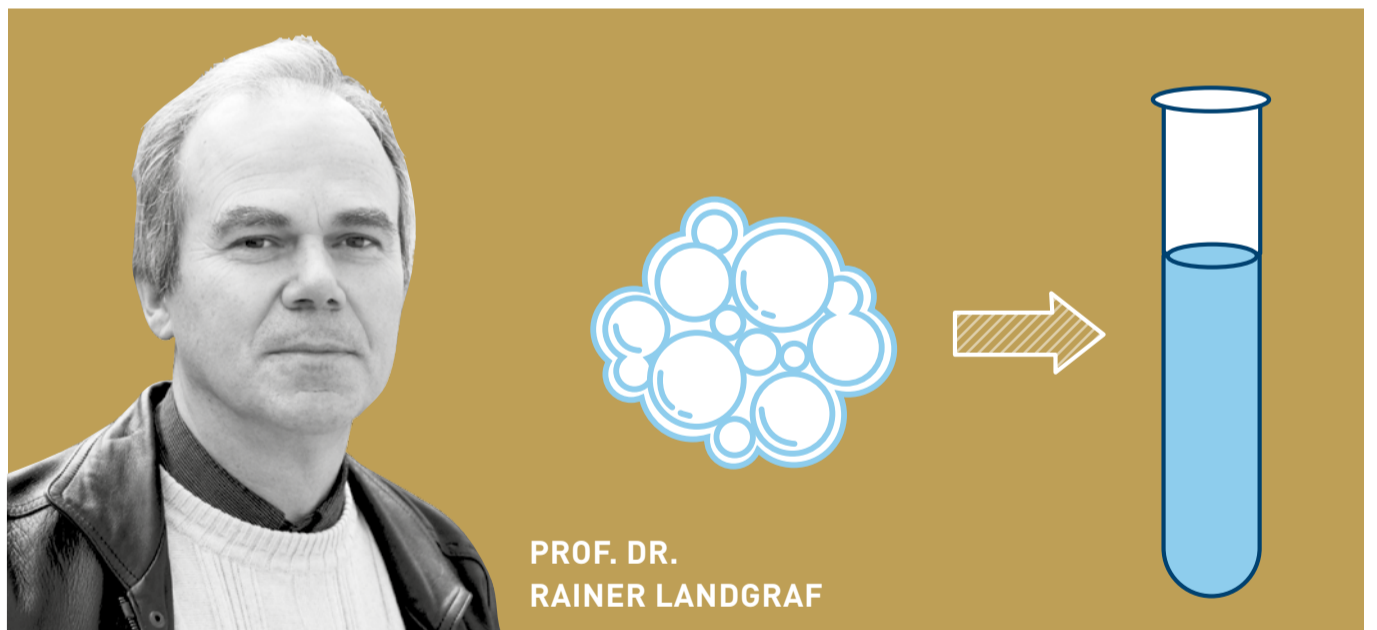
Professor Dr Rainer Landgraf of the Max-Planck-Institute for Psychiatry in Munich, one of the world's leading experts in the area of neuropeptides & behaviour and founder of RIAGNosis, analysed oxytocin in saliva in a TSST study. Oxytocin, a hormone in the pituitary gland and a neuromodulator in the brain (also called the "cuddle hormone") supports social relationships and helps to alleviate anxiety and stress. These as yet unpublished results of OXT measurements in an acute stress situation (TSST) reveal the hormone to be a potentially interesting biomarker for studies. The non-invasive measurement in saliva makes implementation simple.



PROF. DR RAINER LANDGRAF EXPLAINS,

"From studies where oxytocin was given to humans nasally, and supported by findings in animal studies, we know that the hormone supports our social skills, trust, empathy, relationships to our partner and general pro-social behaviour, possibly by being an antagonist of vasopressin, a structurally related peptide. As a result, we postulate that psychiatric disorders such as autism and schizophrenia are associated with a defect in the oxytocin system. Indeed, oxytocin appears to improve social functions in these patients."

The physiological and pharmacological implications of oxytocin described above justify the need to use this peptide as a biomarker for a broad spectrum of emotional and social behaviours. Determinable in saliva, plasma, cerebrospinal fluid and other body fluids, it is possible that this biomarker will advance our understanding of emotional and social regulations, and at the same time, develop into an effective therapy for the causal treatment of psychopathology. All in all, oxytocin is an attractive basic research topic in science, whose findings show promising and meaningful translational outcomes which can be put into practice in the clinic."



PROF. DR. RAINER LANDGRAF

6 OUR PARTNERS

EXPANDING EXPERTISE IN THE AREAS OF PRE-CLINICAL AND IN-VITRO ANALYSIS IN OUR STUDIES BY COLLABORATING WITH BPM.

Short lines of communication facilitate co-operation: since 2014, Dr. Udo Bock has been in the neighbourhood with the company he founded. As a pharmaceutical chemist, he worked in the pre-clinical area for 15 years and was involved with human cell systems (cell

and tissue-based in-vitro test systems). In an Open Innovation Strategy Life Science (OILS), BPM works to support the development of the value creation chain. In this cooperation, we see an excellent opportunity to integrate further questions posed by our sponsors into a study.



VISIT OUR WEBSITES:

WWW.DAACRO.DE // WWW.STRESSZENTRUM-TRIER.DE // WWW.WERDEPROBAND.DE