

# Errata

Nach Drucklegung des Programmheftes haben sich noch einige Korrekturen und Ergänzungen ergeben:

- **Symposien:**

- Symposium I, 4.10.2007, 8:30-10:30 Uhr, Raum A014

**Neue Entwicklungen und Möglichkeiten bildgebender Verfahren**

**Vorsitz: Thomas Dierks / Peter Bartenstein**

G Gründer, Aachen

PET/SPECT und Psychopharmakologie

A Stirn, S Oddo, A Thiel, Frankfurt

Imaging und Psychotherapie

A Federspiel, Bern

Imaging und Psychopathologie

P Vannini, Stockholm/Bern

Combination of PET and MRI for better understanding of pathological brain function

O Pogarell, München

Neurophysiologie und Psychopharmakologie

- Symposium XV, 5.10.2007, 8:30-10:30 Uhr, Raum A119

**Metabolisches Syndrom, Depression, Schlafstörung - neurobiologische Grundlagen und Auswirkungen der Psychopharmakotherapie**

**Vorsitz: Pierre Beitinger / Stefan Kloiber**

(Anm.: Geänderter Vorsitz)

- Satellitensymposium IV, 5.10.2007, 16:00-18:00 Uhr, Raum 140

**Depression und Schlafstörung**

**Melatonener Agonismus - Ein neues Therapiekonzept**

**Vorsitz: HJ Möller, München**

(Anm.: Uhrzeit ist in der Programmübersicht unrichtig mit 16:00-17:45 Uhr angegeben)

- **Poster Lunch II, Freitag, 5.10.2007, 11.45 – 13.45 Uhr, Lichthof**

- 107 Ethics committees and clinical trials in Psychiatry – Experiences with the new approval process after the change of German Drug law (12. AMG Novelle)  
Bergmann K; Fuger J  
Hamburg

The application to Ethics Committees (EC) is mandatory for all studies. The discussion of potential critical issues with the EC is a helpful step and finally the approval can be taken as validation of the ethic considerations of both the sponsor and the investigator. In contrast to that the procedure to obtain such EC approvals was associated with big bureaucratic effort that took long time particularly for multicenter trials in the past. In multinational studies the expected delay had been seen as disadvantage for Germany when selecting countries for study participation.

The presented evaluation is an analysis of experiences with 3 ECs, which reviewed 4 studies in the indications mood disorder, schizophrenia and dementia, in the time after the change of German Drug law in August 2004. The principal investigator (LKP) is now no longer in charge of the application to ECs as this part is handed over to the sponsor's obligations. Further the sponsor only communicates with the leading EC at LKPs institution instead of all individual local ECs. This new set up leads to an EC approval process with less administrative effort and predictable time limits. The specific questions, solutions and timelines are discussed.

In conclusion the generally positive effects of the newly established procedure lead to a more frequent selection of Germany for participation in international registration studies. The experiences also suggest some options where further fine tuning could be helpful.

- 108 Development of computer-assisted self infusion of ethanol (CASE) in humans: the "Freibier" paradigm  
Zimmermann US<sup>1</sup>, Mick I<sup>2</sup>, Vitvitsky V<sup>3</sup>, Mann KF<sup>2</sup>, O'Connor S<sup>3</sup>  
<sup>1</sup>Dresden <sup>2</sup>Mannheim <sup>3</sup>Indianapolis, USA

Human alcohol self-administration studies with oral drinking are flawed by the high variability of resulting breath alcohol concentrations (BrAC). We seek to develop a paradigm with better control over achieved BrAC. We performed a pilot study to test whether healthy subjects are able to understand and use CASE to self-administer alcohol. The CASE system involves intravenous infusion of 6 % ethanol in Ringer's solution via a computer-controlled infusion pump. Subject are guided through the experiment by a computer screen and can order "drinks" any time by pressing a button, or abstain as long as they want. The Freibier paradigm implies that subjects get as much alcohol as they like for free, i.e. without work, pay or other prerequisites. After a short priming period, BrAC rises by exactly 0.075 ‰ upon each button press and declines by 0.01 ‰ per minute thereafter until the next drink is requested. 11 subjects participated in 3 sessions each. Subjects achieved a fairly stable BrAC plateau for prolonged periods of time in most sessions, ranging between 0.25 and 1.0 ‰. The maximum and plateau BrAC varied considerably between the 1st and 2nd test, but was stable between 2nd and 3rd session in most of the subjects. These preliminary data suggest that CASE is a practicable method to investigate human alcohol self-administration and produces considerable alcohol exposure. Its readout appears to be reliable, bearing the potential of being used for scientific questions. Disclosure: This work was supported by NIAAA Grant No. P60 AA007611-20.

- **Sponsoren**

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