

berlin-brandenburgische
AKADEMIE DER WISSENSCHAFTEN

### Registration

Deadline: 25th March, 2008

### Europäische Akademie GmbH

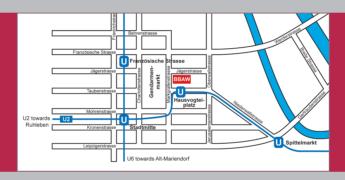
Wilhelmstraße 56 53474 Bad Neuenahr-Ahrweiler Germany

Phone: +49 (0) 26 41 973-300 Fax: +49 (0) 26 41 973-320

e-mail: europaeische.akademie (at) ea-aw.de

http://www.ea-aw.de

### Conference venue



CONFERENCE

CLINICAL RESEARCH IN VULNERABLE POPULATIONS

### Scientific Coordination

### Professor Dr. med. Jörg Fegert

Klinik für Kinder- und Jugendpsychiatrie/Psychotherapie der Universität Ulm

#### Professor Dr. med. Dr. h.c. Günter Stock

Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

#### Dr. med. Felix Thiele

Europäische Akademie GmbH, Bad Neuenahr-Ahrweiler

### Scholarship

A limited number of scholarships may be granted to students. Scholarship includes travel and accommodation expenses. Please send your CV together with reasons for your application by 20th March 2008 to:

Dr. med. Felix Thiele, felix.thiele(at)ea-aw.de

Berlin-Brandenburgische Akademie der Wissenschaften (BBAW), Einstein-Saal Jägerstraße 22/23 10117 Berlin Germany

For further information see:

http://veranstaltungszentrum.bbaw.de/en/directions/map\_bbaw.pdf

3rd – 4th April, 2008

Berlin-Brandenburgische Akademie der Wissenschaften, Einstein-Saal

# Clinical Research in Vulnerable Populations

Research in vulnerable populations, especially in minors and in the mentally ill, is becoming an increasing and urgent problem. For example, a large part of pharmaceuticals which is given to minors and adolescents is not licensed for them: whereas in other cases effective pharmaceuticals have not been developed yet (e.g. dementia). Recently, politicians have taken steps to remedy this deplorable state - e.g. by introducing the regulation (EC) No 1901/2006 on medicinal products for paediatric use. The realisation of this regulation, however, is causing a number of ethical, legal and economical problems: It is debated, to begin with, to what extent and on which ethical and legal foundation risky research in vulnerable populations is acceptable at all. In addition, the realisation of clinical studies in smaller groups of patients (infants, minors, adolescents) is complex, time-consuming, and therefore very costly. Thus, the question arises whether the established ways of drug development are appropriate at all for fulfilling societal needs.

These and further questions will be discussed by experts covering the fields of paediatrics, psychiatry, pharmacology, ethics, law, and economy during the conference at the Berlin-Brandenburgische Akademie der Wissenschaften in Berlin.

### Thursday 3rd April, 2008

#### 13.00 Welcome

Professor Dr. med. Dr. h.c. Günter Stock, Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

Professor Dr. phil. Dr. h.c. Carl Friedrich Gethmann, Europäische Akademie, Bad Neuenahr-Ahrweiler

#### SESSION I Chair: Professor Dr. med. Jörg Feger

### 13.30–14.30 Clinical research in the mentally ill. Medical considerations

Professor Dr. med. Hanfried Helmchen, Freie Universität Berlin

## 14.30–15.30 Clinical research in minors. Medical considerations

Professor Dr. med. Hannsjörg Seyberth, Universität Marburg

15.30-16.00 Break

#### SESSION II Chair: Professor Dr. med. Dr. h.c. Günter Stock

# 16.00–17.00 Ethical concerns of clinical research in vulnerable populations

Jacinta Tan, M.D., Ph.D., University of Oxford

# 17.00–18.00 Clinical research in vulnerable populations. The legal framework

Professor Dr. jur. Gerfried Fischer, Universität Halle

### Friday 4th April, 2008

#### SESSION III Chair: Dr. med. Felix Thiele

# 9.00-10.00 Regulation (EC) No 1901/2006 on medicinal products for paediatric use

Dr. med. Birka Lehmann

Federal Institute for Drugs and Medical Devices,

Bonn

10.00-10.30 Break

# 10.30–11.45 Pharmaceutical research in vulnerable populations. The industry perspective

Dr. med. André Hertkorn,

Boehringer-Ingelheim, Biberach an der Riss

Philippe Auby, M.D., Lundbeck, Paris

### 11.45–12.45 Publicly funded and industry funded researchstrategies in paediatric pharmacology

Benedetto Vitiello, M.D.,

US National Institute of Mental Health, Bethesda

**12.45** Lunch