Preclinical and Clinical Research
for Drug Development

Doctoral Program of
Applied Medical Science (N790)
(Professional Doctorate)

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E-mail: Brigitte.Bloechl-Daum@meduniwien.ac.at

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E-mail: Volker.Wacheck@meduniwien.ac.at
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1. Introduction

Preclinical and clinical research for drug development is an interdisciplinary research area determined to make innovative treatment strategies available for unmet medical needs. A thorough understanding of the development process for novel compounds and the phases of preclinical and clinical testing are a prerequisite for a successful scientific career in the field of drug development. The conduct of preclinical and clinical trials demands a high level of professionalism and only high quality research will allow establishing more effective and safer treatment strategies for patients in the future.

The doctoral program of applied science “Preclinical and clinical research in drug development” will provide a comprehensive training in all major areas of patient-orientated research in drug development. The candidates will be familiarized with the theoretical background of development of a novel compound beginning from the screening in \textit{in vitro} via preclinical animal models up to clinical trial testing (“form bench to bedside”). The main focus will be on the methodology and conduct of preclinical - and clinical trials according to the guidelines of “Good Clinical Practice” (GCP).

Embedded in interdisciplinary research teams with medics, study nurses, molecular biologists and chemists the candidates will plan, design and implement their research projects with scientific integrity in the research areas of cardiovascular medicine, hematology and immunology, experimental oncology, emergency medicine, ophthalmology, pediatrics, pharmacogenetics or imaging. Knowledge of numerous biomedical methods and their application in medical research and practice will be taught. Thus, candidates graduating from the doctoral program of applied science “Preclinical and clinical research in drug development“ will be skilled to apply their theoretical and practical qualifications in high standard clinical research projects within an academic and professional context.
2. Courses

2.1 Basic lecture

The basic lecture is intended to provide the underlying principle of drug development starting from preclinical screening up to clinical testing. In the first semester, the basic course focuses on the theoretical background of preclinical and clinical drug development with a particular emphasis on the design, conduct and analysis of clinical trials.

In the second semester, special scientific aspects and application of clinical research in drug development will be presented to the students by the participating research groups. The detailed program including the titles of the individual lectures will be defined and refreshed annually by the lecturers.

The basic lecture is held in two blocks, one in the first and one in the second semester (4 semester hours = 60 lecture hours).

<table>
<thead>
<tr>
<th>Thematic area</th>
<th>Topics</th>
<th>Lecturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical research</td>
<td>Target identification in vitro</td>
<td>Wacheck</td>
</tr>
<tr>
<td></td>
<td>Mechanism based screening</td>
<td>Wacheck</td>
</tr>
<tr>
<td></td>
<td>Preclinical “Proof of concept” studies</td>
<td>Wacheck</td>
</tr>
<tr>
<td></td>
<td>Animal models</td>
<td>Wacheck</td>
</tr>
<tr>
<td></td>
<td>Target validation</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Design of clinical trials</td>
<td>Phases of clinical trials</td>
<td>Garhöfer</td>
</tr>
<tr>
<td></td>
<td>Study design</td>
<td>Zeitlinger</td>
</tr>
<tr>
<td></td>
<td>Placebo controlled trials</td>
<td>Wolzt</td>
</tr>
<tr>
<td></td>
<td>Masking und Randomisation</td>
<td>Blöchl-Daum</td>
</tr>
<tr>
<td></td>
<td>Ethics in clinical studies</td>
<td>Wolzt</td>
</tr>
<tr>
<td></td>
<td>GCP</td>
<td>Blöchl-Daum</td>
</tr>
<tr>
<td></td>
<td>Study protocol</td>
<td>Zeitlinger</td>
</tr>
<tr>
<td>Conduct of clinical trials</td>
<td>Informed consent</td>
<td>Garhöfer</td>
</tr>
<tr>
<td></td>
<td>Responsibilities at the Investigative site</td>
<td>Wolzt</td>
</tr>
<tr>
<td></td>
<td>Managing a clinical trial at the sponsor site</td>
<td>Jilma</td>
</tr>
<tr>
<td></td>
<td>Responsibility of the ethic committee</td>
<td>Blöchl-Daum</td>
</tr>
<tr>
<td></td>
<td>Adverse event reporting</td>
<td>Blöchl-Daum</td>
</tr>
<tr>
<td></td>
<td>Quality control in clinical trials</td>
<td>Wolzt</td>
</tr>
<tr>
<td>Statistical analysis</td>
<td>Sample size calculation</td>
<td>Herkner/Male</td>
</tr>
<tr>
<td></td>
<td>Outcome parameter</td>
<td>Herkner/Male</td>
</tr>
</tbody>
</table>

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<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Epidemiology</td>
<td>Herkner/Male</td>
</tr>
<tr>
<td>Inferential statistics</td>
<td>Herkner/Male</td>
</tr>
<tr>
<td>Sensitivity analysis</td>
<td>Herkner/Male</td>
</tr>
<tr>
<td>Regulatory affairs</td>
<td>EMEA and FDA</td>
</tr>
<tr>
<td></td>
<td>Blöchl-Daum</td>
</tr>
<tr>
<td>AGES</td>
<td>Blöchl-Daum</td>
</tr>
<tr>
<td>Thematic area</td>
<td>Topics</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cardiovascular Medicine</td>
<td>Vasoactive peptides and antagonists: studies on systemic and regional blood flow</td>
</tr>
<tr>
<td></td>
<td>Nitric oxide synthase inhibition: effects and interactions</td>
</tr>
<tr>
<td></td>
<td>Diabetes mellitus: insulin and disease progress</td>
</tr>
<tr>
<td>Pharmacogenetics and Imaging</td>
<td>Pharmacogenetics and drug development</td>
</tr>
<tr>
<td></td>
<td>PK-PD correlations of anti-infectives</td>
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<tr>
<td></td>
<td>Transporter imaging at the level of the blood brain barrier by small animal PET (µ-PET) and clinical PET in patients</td>
</tr>
<tr>
<td></td>
<td>Clinical studies on genotype / phenotype correlations</td>
</tr>
<tr>
<td></td>
<td>PET in drug delivery</td>
</tr>
<tr>
<td>Experimental Oncology / Molecular Pharmacology</td>
<td>mTOR targeting in cancer</td>
</tr>
<tr>
<td></td>
<td>Target validation by nucleotide therapeutics</td>
</tr>
<tr>
<td></td>
<td>Biomarker endpoints for dose finding</td>
</tr>
<tr>
<td></td>
<td>Angiogenesis biomarker: from bench to bedside</td>
</tr>
<tr>
<td>Ophthalmo-Pharmacology</td>
<td>Vascular risk factors for diabetic retinopathy</td>
</tr>
<tr>
<td></td>
<td>Vascular endothelium in the control of ocular blood flow</td>
</tr>
<tr>
<td></td>
<td>Neuro-vascular coupling</td>
</tr>
<tr>
<td>Hematology and Immunology</td>
<td>LPS model to measure pharmacodynamics of novel compounds</td>
</tr>
<tr>
<td></td>
<td>Platelet hyperfunction in myocardial infarction</td>
</tr>
<tr>
<td></td>
<td>setting new standards for platelet QC</td>
</tr>
<tr>
<td></td>
<td>Therapeutic monitoring of anti-coagulation</td>
</tr>
<tr>
<td>Emergency Medicine</td>
<td>Epidemiology in Emergency Medicine</td>
</tr>
<tr>
<td></td>
<td>Critical issues in emergency medicine clinical trials</td>
</tr>
<tr>
<td>Research in Pediatrics</td>
<td>Methodological issues in clinical trials with children</td>
</tr>
<tr>
<td></td>
<td>Epidemiology in pediatrics</td>
</tr>
</tbody>
</table>
2.2 Journal club and progress report

In the weekly organized journal clubs recent publications will be presented. All clinical research areas of the participating laboratories will be covered. The publications will be critically discussed and evaluated for their scientific impact for clinical drug development. Within the journal club the candidates will be presenting also the progress of their thesis projects. The results will be critically assessed and discussed together with the member of the candidate’s research team. Every 6 months, all candidates of the thesis program “Preclinical and clinical research in drug development” will meet for presenting their thesis progress to all other candidates, their supervisors and the program coordinator. Additionally, students of the thesis program are encouraged to present their research results at the annually held “MUV PhD symposium”. This symposium is aimed to strengthen the interactions between the disciplines and projects within the doctoral programs and to promote collaborations within the MUV. Students preparing a poster of their research results and giving a presentation at the MUV PhD symposium may offset their active participation at the symposium against the thesis seminar in part (i.e. one semester hour).

Journal Clubs are held from the beginning until the end of the doctoral studies, in each semester 2 hours per week (12 semester hours = 180 lecture hours).

<table>
<thead>
<tr>
<th>Title</th>
<th>Semester hours</th>
<th>Supervisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic Pharmacology</td>
<td>2</td>
<td>Garhöfer</td>
</tr>
<tr>
<td>Experimental Oncology / Molecular Pharmacology</td>
<td>2</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Pharmacogenetics and Imaging</td>
<td>2</td>
<td>Zeitlunger</td>
</tr>
<tr>
<td>Cardiovascular Medicine</td>
<td>2</td>
<td>Wolzt</td>
</tr>
<tr>
<td>Preclinical Hematology &amp; Immunology</td>
<td>2</td>
<td>Jilma</td>
</tr>
<tr>
<td>Emergency Medicine</td>
<td>2</td>
<td>Herkner</td>
</tr>
<tr>
<td>Epidemiology and Drug Development</td>
<td>2</td>
<td>Male</td>
</tr>
</tbody>
</table>
2.3 **Thesis seminars**

The thesis seminars will cover selected topics of all areas of preclinical – and clinical research. It is the aim of the student seminars to provide deeper insight into the research projects of the participating research groups. Thus, all clinical research areas of the participating laboratories will be covered.

In order to broaden the insights in preclinical – and clinical research for the program participants we intend to invite on a regular base guest speakers who will highlight “top news” in clinical research for drug development.

Thesis seminars will be held on appointment with the researchers involved. The time and place will be set individually. In total, 12 semester hours have to be completed within the 3 years of the thesis program (2 hours each semester = 12 semester hours = 180 lecture hours). Credits can be accumulated by repeated attendance over several terms.

<table>
<thead>
<tr>
<th>Title</th>
<th>Lecturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuro-vascular coupling in the retina</td>
<td>Garhöfer</td>
</tr>
<tr>
<td>Molecular targeting of cancer</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Molecular Imaging for preclinical pharmacology</td>
<td>Zeitlinger/Langer</td>
</tr>
<tr>
<td>Preclinical pharmacology of haematology and immunology</td>
<td>Jilma</td>
</tr>
<tr>
<td>Drug development in emergency medicine</td>
<td>Herkner</td>
</tr>
<tr>
<td>Pharmacology in pediatrics</td>
<td>Male</td>
</tr>
<tr>
<td>Research in cardiovascular pharmacology</td>
<td>Wolzt</td>
</tr>
<tr>
<td>Pharmacogenetics</td>
<td>Müller</td>
</tr>
<tr>
<td>“Top News” in clinical drug development “</td>
<td>Invited experts</td>
</tr>
</tbody>
</table>
2.4 **Practical seminars**

Practical seminars will be offered as bloc seminars. Participants will be skilled in biomedical methods and the process structure of clinical drug development in an interactive manner. Excursions to leading institutions involved in clinical drug development in Austria will foster the “hands-on” experience of participants and provide insights in daily clinical research practice. The experience gathered in these practical seminars will allow the participants to become conscious of the meaning of clinical research with respect to its scientific and social impact.

Students attending the practical seminars from the third to the sixth semester. In total, 4 semester hours have to be completed (= 60 lecture hours). The practical seminars are offered every other year.

### Third (fifth) semester

<table>
<thead>
<tr>
<th>Topics</th>
<th>Location</th>
<th>Supervisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical animal models and “Proof of concept” studies</td>
<td>Center for Biomedical Research, AKH</td>
<td>Wacheck</td>
</tr>
<tr>
<td>The clinical trial unit</td>
<td>Clin. Pharm., AKH</td>
<td>Wolzt</td>
</tr>
<tr>
<td>Development of modern vaccines: From Bench to Clinical Use</td>
<td>Baxter AG</td>
<td>Tbd (Tauber/Schuller)</td>
</tr>
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</table>

### Fourth (sixth) semester:

<table>
<thead>
<tr>
<th>Topics</th>
<th>Location</th>
<th>Supervisor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Imaging and PET</td>
<td>ARC Seibersdorf / AKH</td>
<td>Langer</td>
</tr>
<tr>
<td>Analysis of experimental Biomarker in clinical trials</td>
<td>Clin. Pharmacology, AKH</td>
<td>Jilma</td>
</tr>
<tr>
<td>Organisation and function of the ethic committee</td>
<td>EC MUV</td>
<td>Blöchl-Daum</td>
</tr>
</tbody>
</table>
3. Recommended literature:


4. Experimental techniques:

<table>
<thead>
<tr>
<th>Methods</th>
<th>Research group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-adhesive and anticoagulatory models in systemic inflammation</td>
<td>Jilma</td>
</tr>
<tr>
<td>Cardiac electrophysiology</td>
<td>Wolzt</td>
</tr>
<tr>
<td>Cardiac performance</td>
<td>Wolzt</td>
</tr>
<tr>
<td>ELISA</td>
<td>Jilma</td>
</tr>
<tr>
<td>FACS</td>
<td>Jilma, Wolzt,</td>
</tr>
<tr>
<td>HPLC-Analysis</td>
<td>Wolzt</td>
</tr>
<tr>
<td>Immunohistochemistry</td>
<td>Wacheck</td>
</tr>
<tr>
<td>In situ Hybridisation</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Laser Doppler flowmetry</td>
<td>Garhöfer</td>
</tr>
<tr>
<td>Retinal vessel diameter measurement</td>
<td>Garhöfer</td>
</tr>
<tr>
<td>Laser interferometric measurement of choroidal blood flow</td>
<td>Garhöfer</td>
</tr>
<tr>
<td>Angiogenesis assays (tube formation, HET CAM)</td>
<td>Wacheck</td>
</tr>
<tr>
<td>RT-PCR</td>
<td>Jilma,</td>
</tr>
<tr>
<td>Microdialysis</td>
<td>Zeitlinger</td>
</tr>
<tr>
<td>Pharmacogenetics</td>
<td>Zeitlinger</td>
</tr>
<tr>
<td>PET and micro PET</td>
<td>Langer</td>
</tr>
<tr>
<td>Preclinical xenograft models</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Selective depletion of blood cells, biocompatibility testing, systemic inflammation and leukocyte emigration</td>
<td>Jilma</td>
</tr>
<tr>
<td>SiRNA und Antisense</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Transdermal bioequivalence</td>
<td>Zeitlinger</td>
</tr>
<tr>
<td>Transient and stable transfection</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Western blotting</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Cell culture</td>
<td>Wacheck</td>
</tr>
<tr>
<td>Statistical analysis</td>
<td>Herkner</td>
</tr>
</tbody>
</table>
### 5. Participating research groups:

<table>
<thead>
<tr>
<th>Supervisor</th>
<th>Department</th>
<th>E-Mail</th>
<th>Positions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gerhard Garhöfer</td>
<td>Clin. Pharm.</td>
<td><a href="mailto:gerhard.garhoefer@meduniwien.ac.at">gerhard.garhoefer@meduniwien.ac.at</a></td>
<td>1</td>
</tr>
<tr>
<td>Bernd Jilma</td>
<td>Clin. Pharm.</td>
<td><a href="mailto:Bernd.Jilma@meduniwien.ac.at">Bernd.Jilma@meduniwien.ac.at</a></td>
<td>2</td>
</tr>
<tr>
<td>Markus Zeitlinger</td>
<td>Clin. Pharm.</td>
<td><a href="mailto:Markus.Zeitlinger@meduniwien.ac.at">Markus.Zeitlinger@meduniwien.ac.at</a></td>
<td>1</td>
</tr>
<tr>
<td>Volker Wacheck</td>
<td>Clin. Pharm.</td>
<td><a href="mailto:Volker.Wacheck@meduniwien.ac.at">Volker.Wacheck@meduniwien.ac.at</a></td>
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</tr>
<tr>
<td>Michael Wolzt</td>
<td>Clin. Pharm.</td>
<td><a href="mailto:michael.Wolzt@meduniwien.ac.at">michael.Wolzt@meduniwien.ac.at</a></td>
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<tr>
<td>Christoph Male</td>
<td>Pediatrics</td>
<td><a href="mailto:christoph.male@meduniwien.ac.at">christoph.male@meduniwien.ac.at</a></td>
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</tr>
<tr>
<td>Markus Müller</td>
<td>Clin. Pharm.</td>
<td><a href="mailto:Markus.Mueller@meduniwien.ac.at">Markus.Mueller@meduniwien.ac.at</a></td>
<td>1</td>
</tr>
</tbody>
</table>
6. Supervisors and research projects

Bernd Jilma
Department of Clinical Pharmacology,
Medical University of Vienna, Währingerürtel 18-20, 1090 Wien
e-mail: Bernd.Jilma@meduniwien.ac.at

Research projects:
The Adhesion Research Group Elaborating Therapeutics (TARGET)
Our focus is to test newly developed drugs in the immunologic and coagulation field.
We try to combine in vitro, ex vivo and in vivo trials to obtain an integrated insight into pathophysiologic processes.

Current Projects:

• Phase I – II drug trials in LPS model to measure pharmacodynamics of novel compounds under standardized conditions of inflammation in healthy volunteers.
• Phase I-III patient trials, to monitor immunmodulation and apoptosis.
• Target on platelets:setting new standards for platelet QC Serotonin effects on platelets
  PFA-100
• Platelet hyperfunction in myocardial infarction
Curriculum Vitae

A.o. Univ. Prof. Bernd Jilma

Address: Department of Clinical Pharmacology, Medical University of Vienna, Währingergürtel 18-20, 1090 Wien

Personal Data
Date of Birth: 19.06.1970
Place of Birth: Vienna
Nationality: Austria

Education
MD, University of Vienna
from – to 1988-1993

Career History
2004 – Vice Chair Department of Clinical Pharmacology
Head Division of Hematology & Immunology

Career-related Activities
2002 – 2005 Member of the Committee on Orphan Medicinal Products
Member of the Scientific Advice Working Party (EMEA)
2006-
Expert to the Austrian Health Agency (AGES Pharmed)
and the EMEA
2008-
Member of the Committee of Advanced Therapeutics
(CAT, EMEA)

Awards
Year 2007 Heribert Konzett Award
2003 Wilhelm Türk Award

Memberships
Austrian Pharmacological Society (APHAR)
American Society of Hematology (ASH)
Sources of funding in last 6 years (2003 – 2008)

Peer-reviewed projects (FWF, EU and equivalent projects)

<table>
<thead>
<tr>
<th>Period</th>
<th>Organization</th>
<th>Short Title</th>
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<tbody>
<tr>
<td>2002</td>
<td>OENBF</td>
<td>Protein C LPS</td>
</tr>
<tr>
<td>2003</td>
<td>FWF</td>
<td>CO-LPS</td>
</tr>
<tr>
<td>2005-6</td>
<td>FWF</td>
<td>Duffy</td>
</tr>
<tr>
<td>2007</td>
<td>Austrian Heart Foundation</td>
<td>Hypertensive Crisis</td>
</tr>
<tr>
<td>2007</td>
<td>OENBF</td>
<td>Clopidogrel resistance</td>
</tr>
</tbody>
</table>

Dr.rer.nat., Dr.sci.med. Dr. techn. or PhD supervisions in last 6 years (2003 – 2008)

Only students in your lab, no external

<table>
<thead>
<tr>
<th>Period</th>
<th>Name of student</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Dr. Magdalena Baumgartner</td>
<td>Pharmacodynamics of recombinant human activated protein C in systemic inflammation</td>
</tr>
<tr>
<td>2003</td>
<td>Dr. Judith Leitner</td>
<td>Antiretroviral therapy and metabolism in HIV infected patients</td>
</tr>
<tr>
<td>2003</td>
<td>Dr. Alexander Spiel</td>
<td>The regulation of the protease activated receptor (PAR-1) in a systemic inflammation model</td>
</tr>
<tr>
<td>2004</td>
<td>Dr. Bily Schmidt</td>
<td>Pharmacodynamic effects of protein C in acute systemic inflammation</td>
</tr>
<tr>
<td>2004</td>
<td>Dr. Doris Bergmaier</td>
<td>The effect of interleukin-6 blockade on tissue factor induced coagulation activation in human endotoxaemia</td>
</tr>
<tr>
<td>2006-</td>
<td>Dr. Jolanta Siller</td>
<td>Thrombin infusion as an experimental DIC model</td>
</tr>
<tr>
<td>2007</td>
<td>Mag. Pharm. Eva Luise Hobl</td>
<td>PK/PD and pharmacogenomics of methotrexate</td>
</tr>
</tbody>
</table>

Publications

>200 peer reviewed publications in scientific journals, 1 book chapter, 8 invited reviews, >20 invited lectures,

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)
First, last or corresponding author manuscripts:


29. Reiter R, Jilma-Stohlawetz P, Horvath M, Jilma B. Additive effects between platelet concentrates and desmopressin in antagonizing the anti-platelet effects of
nucleotide polymorphism Ser128Arg in the E-selectin gene is associated with
31. Reiter RA, Varadi K, Turecek PL, Jilma B, Knöbl P. Changes in ADAMTS13 (von-
Willebrand-factor-cleaving protease) activity after induced release of von
Willebrand factor during acute systemic inflammation. Thromb Haemost
Pharmacokinetics of S/D treated anti-Rhesus D immunoglobulin after
intramuscular injection in healthy volunteers: gender differences in PK. Transfus
33. Marsik C, Jilma B, Joukhadar C, Mannhalter C, Wagner OF, Endler G. The Toll-
like receptor 4 Asp299Gly and Thr399Ile polymorphisms influence the late
dose dexamethasone increases circulating P-selectin and von Willebrand factor
 supra-normal protein C levels on markers of coagulation, fibrinolysis and
inflammation in a human model of endotoxemia. Thromb Haemost 2005;94:1148-
55.
Age and sex modulate metabolic and cardiovascular risk markers of patients after
one year of highly active antiretroviral therapy (HAART). Atherosclerosis
2006;187:177-85.
37. Serebruany V, MD, Malinin A, Ziai W, Atar D, Pokov A, Jilma B, Hanley D.
Dipyridamole decreases protease activated receptor (PAR-1) and annexin-V
binding on platelets of post stroke patients with aspirin non-responsiveness.
38. Leitner JM, Firbas C, Mayr FB, Reiter RA, Steinlechner B, Jilma B. Recombinant
human antithrombin inhibits thrombin formation and interleukin-6 release in
Radosavljevic M. Antiviral therapy decreases GpIIb/IIIa activation of platelets in
40. Spiel A, Mayr FB, Firbas C, Quehenberger P, Jilma B. Validation of rotation
thrombelastography in a model of systemic activation of fibrinolysis and
41. Kotzailias N, Andonovski T, Dukic A, Serebruany VL, Jilma B. Safety and efficacy
of co-administration of the selective serotonin reuptake inhibitor paroxetine and
aspirin -a prospective randomized placebo controlled study. J Clin Pharmacol
2006;46:468-75.
42. Endler G, Marsik C, Jilma B, Schickbauer T, Vormittag R, Wagner OF,
Mannhalter C, Rumpold H, Pabinger I. Anticardiolipin antibodies and overall
43. Marsik C, Halama T, Schlifke I, Mustafa S, Endler G, Jilma B. Polymorphism in
the tissue Factor region is associated with basal but not endotoxin-induced TF-


71. Siller-Matulla JM, Lang I, Christ G, Jilma B. Calcium channel blockers reduce the antiplatelet effect of clopidogrel. J Am Coll Cardiol 2008; in press

73. Siller-Matulla JM, Jilma B. Strain differences in toxic effects of long-lasting isoflurane anesthesia between Wistar rats and Sprague Dawley rats.
74. Food and Chemical Toxicology 2008; in press

Reviews:

Co-author manuscripts:

Invited review:

Selected Key Invited Talks in last 6 years (2003 – 2008)
• Human model of TF-induced coagulation (GTH, Innsbruck, A, February 2003)
• Biomarker Community of Practice (BCoP) Symposium (BMS, Princeton, NJ, USA, 2005, February, 17th)
• Recombinant Antithrombin: Pre-Clinical & Clinical Experience (Satellite Meeting, ISCEM congress in Brussels March 23, 2005)
• Assessing response to aspirin: how much have we achieved ? Symposium: Resistance to antiplatelet drugs: myths and realities. (ESC meeting European Society of Cardiology Stockholm Sept. 3rd 2005)
• Endotoxemia induced coagulation in humans: a translational tool ? (Scientific Subcommittee on Disseminated Intravascular Coagulation; XXI Congress of the International Society on Thrombosis and Haemostasis, Geneva, July 6-12, 2007)
Gerhard Garhöfer

Department of Clinical Pharmacology,
Medical University of Vienna, Währingergürtel 18-20, 1090 Wien
e-mail: Gerhard.Garhoefer@meduniwien.ac.at

Research projects:

The aim of this section is to gain new insights into the pathogenesis of eye diseases,
especially those of vascular origin, and to develop new therapeutic modalities.

Current Projects:

- Ocular blood flow in glaucoma
- Choroidal blood flow in age related macular degeneration
- Vascular risk factors for diabetic retinopathy
- Vascular endothelium in the control of ocular blood flow
- Neuro-vascular coupling

Cooperations:

- Institute de Recherche en Ophthalmologie, Sion
- Center of Biomedical Engineering and Physics
- Department of Ophthalmology, Vienna
Curriculum Vitae

Priv. Doz. Dr. med. univ. Gerhard Garhöfer

Personal Data
Date of Birth: 06.07.1974
Place of Birth: Vienna
Nationality Austria

Education
Sept 2008 Qualification as specialist for Ophthalmology
December 2007 Habilitation for Clinical Pharmacology
March 2000 Graduation from Medical School
1993-2000 Medical School

Career History
current occupation Staff scientist at the Department of Clinical Pharmacology
October 2002 – June 2007 Residency at the Department of Ophthalmology
October 2000 – September scientific co-worker at the Department of Clinical
2002 Pharmacology
May 2000-October 2000 Research associate at the „Institut de Recherche en
Ophthalmologie“ Sion, Switzerland

Career-related Activities
October 2000 – September scientific co-worker at the Department of Clinical
2002 Pharmacology

Awards
Year
2008 Endothelin Research Award

Memberships
Austrian Ophthalmological Society European Association for Vision and Eye
International Society of Eye Research Research
Sources of funding in last 6 years (2003 – 2008)

Peer-reviewed projects (FWF, EU and equivalent projects)

<table>
<thead>
<tr>
<th>Period</th>
<th>Organization</th>
<th>Short Title</th>
<th>K€/year</th>
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<tbody>
<tr>
<td>2003-2005</td>
<td>FWF</td>
<td>Effect of histamine on ocular blood flow</td>
<td>42</td>
</tr>
<tr>
<td>2005-2006</td>
<td>Jubiläumsfonds der Österreichischen Nationalbank</td>
<td>Auswirkungen von intravenös verabreichtem Clonidin auf den Augendruck und die Augendurchblutung im Vergleich zu topisch angewendeten Clonidin und Brimonidin während isometrischer Übungen</td>
<td>35</td>
</tr>
<tr>
<td>2007-2008</td>
<td>Medizinisch-Wissenschaftlicher Fonds des Bürgermeisters der Bundeshauptstadt Wien</td>
<td>Gibt es einen Unterschied in Flackerlicht induzierter Gefäß erweiterung zwischen Rauchern und Nichtrauchern</td>
<td>21</td>
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</table>

Dr.rer.nat., Dr.sci.med. Dr. techn. or PhD supervisions in last 6 years (2003 – 2008)

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<tr>
<th>Period</th>
<th>Name of student</th>
<th>Topic</th>
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<tr>
<td>2008</td>
<td>Sperl Philipp</td>
<td>Neue Therapiekonzepte bei Glaukom</td>
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</table>

Publications
39 peer reviewed publications in scientific journals, 4 book chapters, 10 invited lectures, 0 patents

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)


Invited Talks in last 6 years (2003 – 2008)
Christoph Male

Department of Paediatrics
Medical University of Vienna, Währingergürtel 18-20, 1090 Wien
e-mail: Christoph.Male@meduniwien.ac.at

Research projects:

Our main focus is to study the epidemiology, diagnosis and prevention of thrombembolic events in children. Studies for the following paediatric thrombosis research projects are ongoing:

- Monitoring of anticoagilation in children
- Monitoring of pharmacotherapy in children with coagulation disorder
- Immunological and functional characterization of antiphospholipid antibodies

Research projects are performed in close collaboration with research groups within the Dept of Paediatrics (e.g. nephrology) and Dept of Clinical Pharmacology.

A general focus of the research group is dedicated to clinical trial design and support for statistical analysis of research data.
Curriculum Vitae

Ao. Prof. Dr. med. univ. Christoph Male

Career History

current position
Associate Professor of Paediatrics, Dept. Paediatrics, Medical University of Vienna (MUW)
Head of Haemostasis & Thrombosis Unit

Biostatistical reviewer, Ethics Review Board, Vienna Municipal Hospitals

Since 2007
Member of the Paediatric Committee (PDCO)

Education

1987 Medical Doctor - MUW
1992 Diploma in General Medicine
1997 Diplaom in Paediatrics
2007 Diploma in Paediatric Cardiology

2000 Master of Science in Health Research Methodology, McMaster University, Hamilton, Ontario, Canada

1990-96 Research Fellowship in Paediatric Nutrition, 1990-96, Dept. Paediatrics, MUW

1998-2000 Research Fellowship in Paediatric Thrombosis, McMaster University, Hamilton, and Hospital for Sick Children, Toronto, Ontario, Canada

2006 Evaluation of Medicinal Products in Children, 2006, Eudipharm, Brussels, Belgium
Sources of funding in last 6 years (2003 – 2008)

Peer-reviewed projects (FWF, EU and equivalent projects)

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<th>Period</th>
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Dr.rer.nat., Dr.sci.med. Dr. techn. or PhD supervisions in last 6 years (2003 – 2008)

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<th>Topic</th>
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<tr>
<td>2006 -</td>
<td>Hratsch Karapetian, N090</td>
<td>Thrombembolic events and cardiac catheterization</td>
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Publications
39 peer reviewed publications in scientific journals, 4 book chapters, 10 invited lectures, 0 patents

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)


15: Chan AK, Patel S, Male C, Berry LR, Mitchell LG. Activated protein C generation is greatly decreased in plasma from newborns compared to adults in the presence or absence of endothelium. Thromb Haemost. 2004 Feb;91(2):238-47.


Markus Müller

Department of Clinical Pharmacology,
Medical University of Vienna, Währingergürtel 18-20, 1090 Wien
e-mail: Markus.Mueller@meduniwien.ac.at

Research projects:
It is the aim to perform clinical pharmacokinetic studies in patients and healthy volunteers. Beside traditional pharmacokinetics (e.g. bioequivalence studies) our main focus is the investigation of the drug distribution process in vivo. For that purpose we employ novel innovative tools to study drug distribution in vivo, notably microdialysis (e.g. transdermal bioequivalence, lung- and tumor- drug level measurements) and radiopharmaceutical techniques like 14C mass balance approaches and 153Sm and 99Tc labelling for gastrointestinal transit / absorption studies.

Current projects:

- microPET studies in small animals for distribution studies of NCE
- microdialysis studies (e.g. transdermal bioequivalence, lung- and tumor- drug level measurements)
- 153Sm and 99Tc labelling for gastrointestinal transit / absorption studies
**Curriculum Vitae**

**Prof. Dr. med. univ. Markus Müller**

Address Dept. of Clinical Pharmacology, Medical University Vienna

**Personal Data**

Date of Birth: 23.08.1967  
Place of Birth: Klagenfurt  
Nationality: Austria

**Education**

2005  
Emergency Physician  

2000 – 2001  
University of Florida, GAINESVILLE, USA, College of Medicine - Department of Pharmacology and College of Pharmacy - Department of Pharmaceutics

1995  
Postdoctoral Research Fellowship, Sahlgrenska University Hospital, GÖTEBORG, SWEDEN, Department of Medicine and Lundberg Laboratory for Diabetes Research

1993 – 1999  
Resident in Internal Medicine ("Facharzt") University of Vienna Medical School, Vienna General Hospital AKH; special fields covered: Emergency Medicine, Oncology, Endocrinology and Metabolism, Infectious Diseases and Chemotherapy, Angiology, Clinical Pharmacology

1993  
M.D. (University Vienna) Graduation with highest possible honours (*sub auspiciis praesidentis rei publicae*),

1987  
Research Fellowship, LUND, SWEDEN, Department of Cell and Tissue Research (now: “Neuroendocrine Cell Biology”)

**Career-related Activities**

Since 2002  
Professor and Chairman, Department of Clinical Pharmacology, Medical University Vienna  

Since 2006  
Chairman, Educational Advisory Board, Vienna School of Clinical Research

Since 2002  
Chairman of the Pharmacological Expert Committee, Association of Austrian Social Insurance Institutions

1998/2001  
Associate Professor (Internal Medicine (2001) and Clinical Pharmacology (1998))

**Awards**

2004  
Investigator Award of the American College of Clinical Pharmacology (ACCP) in acknowledgement of innovations in clinical pharmacology trials

1997  
Denk Award of the Austrian Society of Hematology and Oncology

1996  
Bilroth Award of the Austrian Chamber of Physicians
Memberships
Austrian Society of Internal Medicine, Austrian pharmacological Society, American Society of Clinical Pharmacology and Therapeutics, European Association of Clinical Pharmacology

Sources of funding in last 6 years (2003 – 2008)

<table>
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<tr>
<th>Period</th>
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<th>Short Title</th>
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<tbody>
<tr>
<td>2008</td>
<td>EU FP 7</td>
<td>Euripides (Pet Imaging)</td>
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<tr>
<td>2008</td>
<td>FWF</td>
<td>SFB (Transporter Research)</td>
</tr>
</tbody>
</table>

Publications
> 180 peer reviewed publications in scientific journals, > 40 invited lectures, 2 patents

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)

2003


2005


2006


80. Mittermayer F, K Krzyzanowska, M Exner, W Mlekusch, J Amighi, S Sabeti, E Minar, M Müller, M Wolzt, M

2007


2008


**Invited Talks in last 6 years (2003 – 2008)**

> 30 (including invited talks at US-FDA, Royal Society London, Univ. Cambridge UK, American College of Clinical Pharmacology etc.)
Volker Wacheck

Department of Clinical Pharmacology,
Medical University of Vienna, Währingergürtel 18-20, 1090 Wien
e-mail: Volker.Wacheck@meduniwien.ac.at

Research projects:

The goal of our research group “Experimental oncology/Molecular Pharmacology” is to study the functional relevance of oncogenic factors and possibilities to overcome treatment resistance of solid tumors by hampering oncogene function using novel gene specific "small molecules" (e.g. antisense oligonucleotides, siRNA). These research efforts comprise in vitro-, in vivo studies and clinical trials.

The second focus of our group is dedicated to the implementation of biomarkers in preclinical and clinical trials for optimizing drug development in oncology.

- Xenotransplantation models for a variety of solid tumors for proof of concept for "molecular targeting" compounds (e.g. Antisense oligonucleotides and siRNA, mTOR inhibitors, VEGF targeting TKI, NFkB modulators)
- CEC/CEP for monitoring anti-angiogenic treatment in vivo and in clinical trials
- CTC for monitoring drug activity in oncology trials
- ERCC-1 as biomarker for platin resistance
- Interplay of bcl-2 family members and mTOR pathway for chemoresistance in cancer
- PKM2 targeting metabolism and cancer
- Characterization of novel apoptosis inducing agents
Curriculum Vitae

Dr. med. univ. Volker Wacheck

Address
Department of Clinical Pharmacology, Section of Experimental Oncology/Molecular Pharmacology, Medical University Vienna, Austria

Personal Data
Date of Birth: 09 March 1969
Place of Birth: Mainz, Germany
Nationality: German

Education
2007 – present
Training in Hematology/Oncology, AKH Vienna

2004-2007
Postgraduate diploma in Clinical Research
University of Vienna and Vienna School of Clinical Research, Vienna, Austria

1999-2007
Clinical Training in Internal Medicine and Clinical Pharmacology
• Department of Emergency Medicine
• Department of Oncology
• Department of Clinical Pharmacology
(attending physician since 2001)

Career History
since 2001
Head, Section of Experimental Oncology/Molecular Pharmacology
Department of Clinical Pharmacology, Medical University Vienna, Austria

1997 – 2001
Postdoctoral Associate
Department of Clinical Pharmacology, Medical University Vienna, Austria

Career-related Activities
since 2005
Co-Organizer of the “Doctoral studies of medical science”
program: "Preclinical and clinical research for drug development",

since 2002 Organizer of the “Forum Drug Therapy” postgraduate university lecture, AKH Vienna

since 2001 Lecturer and Tutor at “Vienna School of Clinical Research”, Vienna, Austria

since 2001 Referee for the ethic committee, University of Vienna and Salzburg, Austria

Awards

2003 ”AACR-Pfizer Scholar-in-Training Award”, AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, Boston, USA

2003 "Research Award", Vienna fund for innovative and interdisciplinary Cancer Research

1998 "Dissertationspreis", Austrian Society for Dermatology (ÖGDV)

Memberships

Österreichische Pharmakologische Gesellschaft (Austrian Pharmacological Society)
American Association for Cancer Research (AACR)

Sources of funding in last 6 years (2003 – 2008)

<table>
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<tr>
<th>Period</th>
<th>Organization</th>
<th>Short Title</th>
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<tr>
<td>2008-2009</td>
<td>Bürgmeister Fonds der Stadt Wien</td>
<td>ERCC1 as biomarker</td>
</tr>
<tr>
<td>2007-2008</td>
<td>ÖNB</td>
<td>Biomarker development for drug development in oncology</td>
</tr>
<tr>
<td>2006-2009</td>
<td>EU FP6</td>
<td>Intranasal Influenza H5N1 vaccine</td>
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<tr>
<td>2005-2010</td>
<td>EU FP6</td>
<td>Live attenuated replication defecicient influenza vaccine</td>
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Dr.rer.nat., Dr.sci.med. Dr. techn. or PhD supervisions in last 6 years (2003 – 2008)

<table>
<thead>
<tr>
<th>Period</th>
<th>Name of student</th>
<th>Topic</th>
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<tr>
<td>2006-2007</td>
<td>Doris Höffmayer, MD</td>
<td>SphK1 targeting for chemosensitization</td>
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<tr>
<td>2004-2007</td>
<td>Doris Losert, Dr rer nat</td>
<td>siRNA for targeting chemoresistance</td>
</tr>
<tr>
<td>2004-2005</td>
<td>Daniel Cejka, MD</td>
<td>Mcl-1 antisense for gastric cancer</td>
</tr>
<tr>
<td>2005-2006</td>
<td>Thorsten Füreder, MD</td>
<td>Choleaterol derivatives and chemoresistance</td>
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</tbody>
</table>
Publications
32 peer reviewed publications in scientific journals, 1 patent

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)

First, last or corresponding author manuscripts:
• Sieghart W, Fuereder T, Schmid K, Cejka D, Werzowa J, Wrba F, Wang X,


**Co-author manuscripts:**

- Allen M, Pratscher B, Roka F, Krepler C, Wacheck V, Schofer C, Pehamberger,


Invited Talks in last 6 years (2003 – 2008)
28 invited talks
Michael Wolzt

Department of Clinical Pharmacology,
Medical University of Vienna, Währingerürtel 18-20, 1090 Wien
e-mail: Michael.Wolzth@meduniwien.ac.at

Research projects:

We are combining evaluation and validation of novel non-invasive measurement techniques with cardiovascular drug profiling, i.e. simultaneous recordings of pharmacodynamic effects in different vascular beds, and in vivo investigations of pathophysiological causes, clinical consequences and treatment possibilities in clinical studies.

Current Projects:

• Vasoactive peptides and antagonists: studies on systemic and regional blood flow
• Nitric oxide synthase inhibition: effects and interactions
• Diabetes mellitus: insulin and disease progression
• Blood coagulation: release of mediators and characterisation of inhibitors
Curriculum Vitae

A.o. Univ. Prof. Michael Wolzt

Address
Allgemeines Krankenhaus Wien, Department of Clinical Pharmacology
Währinger Gürtel 18-20I, A-1090 Wien, Austria
Tel +43 1 40400 2981

Personal Data
Date of Birth: 5 Jul 1967
Place of Birth: Vienna, AUT
Nationality Austria

Education
Since 2005 Specialist training in Endocrinology and Metabolism
From 1999 to 2002 Specialist training in Cardiology
From 1991 to 1999 Specialist training in General (Internal) Medicine
From 1985 to 1991 University of Vienna Medical School 1985 - 91 received M.D. (19.6. 1991)

Career History
1999 Associate Professor of Internal Medicine
1999 Registered consultant (“Facharzt”) in General (Internal) Medicine
From 1997 to 1998 Research fellowship, University College London,
The Wolfson Institute for Biomedical Research (Cruciform Project)

Career-related Activities
Since 2005 Austrian delegate to ECRIN, European Clinical Research Infrastructure Network
Since 2004 European Expert, European Agency for the Evaluation of Medicinal Products (EMEA), nominated by the Austrian competent authority, Bundesministerium für Gesundheit und Frauen (BMGF)
Since 2001
Vienna School of Clinical Research, course director and faculty member of various training courses; Member Educational Advisory Board

Since 2000
Member of the Research Ethics Committee at the Medical University of Vienna and Vienna General Hospital, vice-chair (since 2006)

Awards
1997
Erwin Schrödinger Fellowship by the Austrian Science Fund: The Wolfson Institute for Biomedical Research (Cruciform Project), University College London, UK

1998
Science Award of the HOECHST-Foundation Austria (for Diabetes 1997;46:653-8)

2000
Poster Prize, 36th Annual Meeting of the European Association for the Study of Diabetes (J. Pleiner et al.)

2000
Science Award of the ERSTE BANK der Österreichischen Sparkassen AG (for J Biol Chem 1999;274:28983-90)

2003
Poster Prize, 31st Annual Meeting of the Austria Diabetes Association (F. Mittermayer et al.)

2003
Science Award of the ERSTE BANK der Österreichischen Sparkassen AG (for Diabetes 2003;52:16-20)

2006
Science Award of the Austrian Society for Cardiology (Österreichischer Kardiologenpreis; for Atherosclerosis 2006)

2006
Eli Lilly Research Award (for Diabetologia 2006; 49:1909-14)

2007
Science Award of the Austrian Pediatric Society (Österreichische Gesellschaft für Kinder- und Jugendheilkunde; for Arterioscler Thromb Vasc Biol 2006;26:2541-6)

2007

2008

2008
Theodor-Billroth-Award of the Ärztekammer für Wien (for...
Memberships
Arbeitsgemeinschaft für Angewandte Humanpharmakologie (Association for Applied Human Pharmacology)
Deutsche Gesellschaft für Klinische Pharmakologie und Therapie e.V. (German Society for Clinical Pharmacology and Therapeutics)
Österreichische Gesellschaft für Innere Medizin / Wien und Burgenland (Austrian Society for Internal Medicine)
Österreichische Kardiologische Gesellschaft (Austrian Society for Cardiology)
Österreichische Pharmakologische Gesellschaft (Austrian Pharmacological Society)

Sources of funding in last 6 years (2003 – 2008)

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<tr>
<th>Period</th>
<th>Organization</th>
<th>Short Title</th>
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<tr>
<td>2006 - 2008</td>
<td>EU FP6 European Clinical Research Infrastructures Network and biotherapy facilities (ECRIN-TWG)</td>
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<tr>
<td>2008 - 2010</td>
<td>EU FP7 European Clinical Research Infrastructures Network and biotherapy facilities: preparation phase for the infrastructure (ECRIN-PPI)</td>
<td></td>
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<tr>
<td>2008 - 2011</td>
<td>Wiener Wissenschafts-, Forschungs- und Technologiefonds (WWTF) Therapy of ischemia-reperfusion injury by Heme Oxygenase-1 induction in skeletal muscle and ischemic kidney</td>
<td></td>
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<tr>
<td>2008 - 2014</td>
<td>EU, Innovative Medicine Initiative NEBRIC; Network of European Biomedical Research Infrastructures Consortium</td>
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Dr rer nat., Dr sci med. Dr techn. or PhD supervisions in last 6 years (2003 – 2008)

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<tr>
<th>Period</th>
<th>Name of student</th>
<th>Topic</th>
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<tr>
<td>2005 - 2007</td>
<td>Christina Dückelmann</td>
<td>Dr.med.sci.</td>
</tr>
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</table>

Publications
203 peer reviewed publications in scientific journals, 5 books / book chapters

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)
First, last or corresponding author manuscripts:


Boström SL, Hansson GF, Sarich TC, Wolzt M. The inhibitory effect of melagatran, the active form of the oral direct thrombin inhibitor ximelagatran, compared with enoxaparin and r-hirudin on ex vivo thrombin generation in human plasma. Thromb Res 2004;113:85-91


Haemost 2004;91:1090-6


Mittermayer F, Prusa AR, Pollak A, Wolzt M. Umbilical vein plasma concentrations of asymmetrical dimethylarginine are increased in male but not female neonates delivered preterm. Early Hum Dev 2006;82:421-424


Nutr 2006;43:548-9
Gouya G, Reichardt B, Bidner A, Weissenfels R, Wolzt M. Partial reimbursement of prescription charges for generic drugs reduces costs for both health insurances and patients. Wien Klin Wochenschr 2008;120:89-95
Dückelmann C, Mittermayer F, Haider DG, Altenberger J, Wolzt M. Plasma asymmetric

Co-author manuscripts:


Krzyzanowska K, Mittermayer F, Shnawa N, Hofer M, Schnabler J, Etmüller Y, Kapiotis S, Wolzt M, Schernthaner G. Asymmetrical dimethylarginine is related to renal function,
chronic inflammation and macroangiopathy in patients with Type 2 diabetes and albuminuria. Diabet Med 2007;24:81-6


Andreas M, Zeisler H, Handisurya A, Wolzt M, Kautzky-Willer A. NT-proBNP is decreased in severe gestational diabetes mellitus. (in press)
Markus Zeitlinger

Department of Clinical Pharmacology,  
Medical University of Vienna, Währingergürtel 18-20, 1090 Wien  
e-mail: Markus.Zeitlinger@meduniwien.ac.at

Research projects:

Our mission is to perform clinical studies in healthy volunteers and patients to elucidate the impact of genetic variants and various pathophysiological states on pharmacokinetics and pharmacodynamics.

- Our main focus is the study of the drug distribution process by employing techniques to measure target site distribution directly, i.e. PET or microdialysis. (e.g. BBB penetration of a 11C-labeled anti-amyloid drug in a healthy volunteers and Alzheimers patient

- Detection of genes with differential response patterns during endotoxemia with different response patterns after treatment with the statin drugs

Current Projects

- PK-PD correlations of anti-infectives
- Transporter imaging at the level of the blood brain barrier by small animal PET (µ-PET) and clinical PET in patients
- Alzheimer plaque imaging
- Clinical studies on genootype / phenotype correlations
- Expression profiling studies on drug effects in healthy volunteers
Curriculum Vitae

Priv. Doz. Dr. med. univ Markus Zeitlinger

Address
Department of Clinical Pharmacology, Medical University of Vienna, Währinger Gürtel 18-20, A-1090 Vienna, Austria

Personal Data
Date of Birth: April 9, 1975
Place of Birth: Vienna, Austria
Nationality Austria

Education
Resident in Internal Medicine and Clinical Pharmacology, Medical University of Vienna
10/2001-present

Post graduate education „Clinical research“ at the Vienna School of Clinical Research

Resident in Internal Medicine, Orthopaedics and Ear, Nose and Throat, Army Hospital, Vienna
12/2000-09/2001

Student at the University of Vienna Medical School (M.D.)
1993-2000

Career History
Associate Professor of Clinical Pharmacology (Venia legendi for Clinical Pharmacology, “Habilitation”) 16.5.2008
Diploma in Clinical Research 11.10.2007

Career-related Activities
European Expert of the European Medicines Agency (EMEA) 5/2005-present
Expert of the Competent Authority of Austria “Bundesamt für Sicherheit im Gesundheitswesen” (BASG) 6/2006-present
Memberships
International Society of Anti-Infective Pharmacology (ISAP)
Österreichische Pharmakologische Gesellschaft (Austrian Pharmacological Society, APHAR)
Österreichische Gesellschaft für antimikrobielle Chemotherapie (ÖGACH, Austrian Society of Antimicrobial Chemotherapy)
Österreichische Gesellschaft für Infektionskrankheiten (ÖGI, Austrian Society of Infectious Diseases)

Sources of funding in last 6 years (2003 – 2008)

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Dr.rer.nat., Dr.sci.med. Dr. techn. or PhD supervisions in last 6 years (2003 – 2008)

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<tr>
<td>Since 2007</td>
<td>Claudia Wagner</td>
<td>Microdosing in Clinical Drug Development</td>
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<td>Since 2007</td>
<td>Shaip Krasniqi</td>
<td>Tissue Pharmacokinetics of Eritromycin and Azithromycin</td>
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Publications
35 peer reviewed publications in scientific journals, 2 book chapters, 5 invited lectures
Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)

First, last or corresponding author manuscripts:


Co-author manuscripts:


Invited Talks in last 6 years (2003 – 2008)

1) 4th International Symposium Microdialysis in Drug Research and Development: Lung Microdialysis (Vienna 2004)
2) 2. Österreichischen Infektionkongress „Pneumonie“: Pro und Contra PK/PD in der Lunge (Leogang 2008)
3) Berliner Mikrodialyse-Symposium 2008: Mikrodialyse zur Evaluierung antimikrobieller Aktivität am Zielort (Berlin 2008)
4) EHLRLICH II –2nd World Conference on Magic Bullets: Pharmacokinetics of Macrolides and Ketolides – where is the drug and how do we measure (Nürnberg 2008)
5) 13th Scientific Meeting of the European Society of Chemotherapy: How Breakpoints Arise - the Pharmacological Point of View (Vienna 2008)
7. Lecturers

Curriculum Vitae

Brigitte Blöchl-Daum

Academic degrees: MD, Associate Professor of Clinical Pharmacology

Address: Universitätsklinik für Klinische Pharmakologie
Allgemeines Krankenhaus Wien
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Tel: (+43 1) 40400 2981
Fax (+43 1) 40400 2998
E-Mail: brigitte.bloechl-daum@meduniwien.ac.at

Current Position:

1996 - 2000, 2003 - Vice Chair, Department of Clinical Pharmacology, Medical University of Vienna

1992 - Registered Consultant in Internal Medicine

1996 - Registered Consultant in Clinical Pharmacology

Other Professional Activities:

2005 - President; Clinical Pharmacology Section of the Austrian Pharmacologic Society

2005 - Austrian Delegate to the Committee for Orphan Medicinal Products (COMP) at the European Agency for the Evaluation of Medicinal products (EMEA)

2006 - Member of the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use (CHMP) at the European Agency for the Evaluation of Medicinal products (EMEA)

2005 - Austrian Representative to the European Network of National Programs of the European and Developing Countries Clinical Trials Partnership

1996 - 1999, 2003 - Member of the Ethics Committee of the Medical University of Vienna
2006 - Member of the Scientific Advisory Board of the Austrian Agency for Health and Food Safety (AGES)

2007- Member of the Austrian Pharmaceutical Appeals Committee

2003 - Senior lecturer at the Vienna School of Clinical Research (VSCR)

2006 - Member of VSCR Educational Advisory Board

1993 - 1999 Member, Medical Faculty Senate of the University of Vienna

Education:

1978-1985 M.D., Vienna University Medical School, Vienna, Austria

Clinical Training:

1988 - 1992 Resident: Department of Internal Medicine (Oncology, Gastroenterology, Endocrinology, Cardiology), Vienna University Hospital, Vienna, Austria

1986 - 1988 Senior House Officer, Auckland University Hospital, Auckland, New Zealand
Depts. of Surgery, Accident and Emergency, Orthopedics, Internal Medicine, Paediatrics, Gynaecology & Obstetrics

1985 – 1986 Resident: Department of Chemotherapy, Vienna University Hospital

Research Experience

1992 - 1996 Consultant, Department of Clinical Pharmacology, Vienna Cooperating Consultant with the Department of Oncology, Vienna University Hospital

Licenses, Diplomas:

1996 D.M. Thesis (Habilitation) for Clinical Pharmacology (Vienna, Austria)

1996 Medical License (Clinical Pharmacologist), Austria

1992 Medical License (Internist), Austria
1992 Diploma, Clinical Investigator, Austrian Medical Association

Marital Status: married 1986 Dr.-Ing. Rainer Bloechl,
Children: Vivien Cornelia (1997)
           Colin Herbert (1999)


Selected Publications


Curriculum Vitae

Harald Herkner
A.o. Univ. Prof.

Address
Department of Emergency Medicine, MUW/ AKH
Währinger Gürtel 18-20, A-1090 Vienna, Austria

Personal Data
Date of Birth: 20.2.1969
Place of Birth: Austria
Nationality Austrian

Education
2005-2007 MSc Epidemiology University of London/ LSHTM
2002-2005 Specialist training intensive care medicine
1995-2002 Specialist training internal medicine
1987-1994 Graduate training Medicine

Career History
2003- recent Consultant at Department of Emergency Medicine
AKH/MUW Vienna

Career-related Activities
2002- recent Editor Cochrane Anaesthesia group

Peer reviewed manuscripts in last 6 years (2003 – 2008, original research and reviews)
Laggner AN. Lunar phases are not related to the occurrence of acute myocardial infarction and sudden cardiac death. Resusc 2003;56:187-189 (Short communication)


Wagner A, Herkner H, Schreiber W, Bur A, Woisetschlager C, Stix G, Laggner AN, Hirschl MM. Ramipril prior to thrombolysis attenuates the early increase of PAI-1 in
patients with acute myocardial infarction. THROMB HAEMOST 2002;88(2):180-185


