

ALTEX

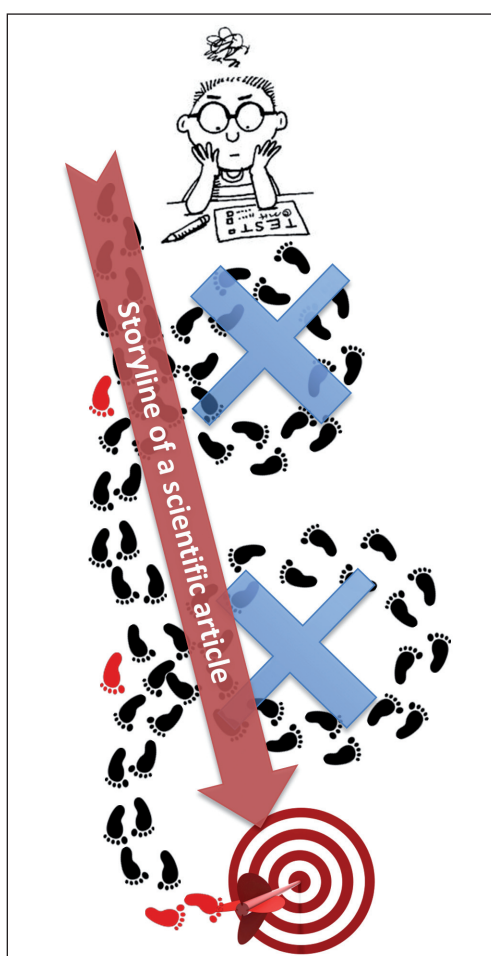
ALTERNATIVES TO ANIMAL EXPERIMENTATION

Food for thought ...

Thomas Hartung:
**Look back in anger –
what clinical
studies tell us about
preclinical work**

Barae Jomaa,
Jac M. M. J. G. Aarts,
Laura H. J. de Haan,
Ad A. C. M. Peijnenburg,
Toine F. H. Bovee,
Albertinka J. Murk, and
Ivonne M. C. M. Rietjens:
**In vitro pituitary and
thyroid cell proliferation
assays and their
relevance as alternatives
to animal testing**

Sebastian Polak:
**In vitro to human
in vivo translation –
pharmacokinetics
and pharmacodynamics
of quinidine**



Karin Dreisig, Camilla Taxvig,
Mia Birkhøj Kjærstad, Christine
Nellemann, Ulla Hass,
and Anne Marie Vinggaard:
**Predictive value of cell
assays for developmental
toxicity and embryotoxicity
of conazole fungicides**

Miriam N. Jacobs,
Susan C. Laws, Kate Willett,
Pat Schmieder, Jenny Odum,
and Toine F. Bovee:
**In vitro metabolism
and bioavailability tests
for endocrine active
substances: What
is needed next for
regulatory purposes?**

t4 workshop report:
Louise Parks Saldutti, Bruce K.
Beyer, William Breslin, et al.:
**In vitro testicular toxicity
models: Opportunities
for advancement via
biomedical engineering
techniques**

Comments
Workshop report
Erratum
Calendar of events
Corners
News



**Dear readers,**

Upon going to press we received the news that India has announced a ban on animal experiments for cosmetics and their ingredients, aligning India's policy with that of the European Union. Testing strategies for new cosmetic products must be agreed by the Central Drug Standards Control Organisation and conform to the Bureau of Indian Standards' non-animal standards. A violation of this ban can lead to up to ten years imprisonment, a hefty fine, or both. Imported cosmetic products are not affected by the ban.

In the USA the lastest Gallup poll (<http://www.gallup.com>) performed in May 2013 showed a 9% decline in the number of Americans that find medical testing on animals morally acceptable since 2001 (from 65 to 56%). Being among the largest changes documented, this issue may gain increasing weight in politics in future and feed into upcoming legislative changes, such as the modernization of the Toxic Substances Control Act, for which reform bills recently have been introduced before the Senate.

In this vein, the U. S. Environmental Protection Agency has just issued new guidance on the assessment of pesticides aiming to reduce use of animals which can be as high as 10,000 animals per substance; the NIH has announced plans to retire 90% of its chimpanzees from research; and a recent article by Maffini et al. in *Comprehensive Reviews in Food Science and Food Safety* criticizing the U. S. Food and Drug Administration's program to assess the safety of food additives may trigger a substantial update of this program that will hopefully also follow the 3R principle and promote the use of current and future alternatives to animal experiments.

In the current issue of ALTEX, Thomas Hartung asks in his Food for thought ... why 95% of drug candidates fail to prove safety and efficacy in clinical trials. It seems that preclinical studies, both animal and *in vitro* studies, are often of little relevance or poor quality, building up hopes that are later dashed, sometimes even causing unforeseen serious side effects. He gives examples of studies that have tried and failed to reproduce seminal preclinical data and of studies that show how commonly laboratory cell lines are contaminated by mycoplasma or overgrown by other cell lines.

Miriam Jacobs et al. discuss the testing of endocrine active substances and make recommendations for the incorporation of metabolic enzyme systems and toxicokinetic aspects to improve the predictivity of *in vitro* assays for identifying endocrine active substances and endocrine disruptors. Louise Saldutti et al. report on a t4 workshop focusing on *in vitro* testicular toxicity tests and describe both the state of the art and the opportunities offered these tests, especially by bioengineering techniques.

Karin Dreisig and colleagues challenge a batch of *in vitro* assays for developmental toxicity and embryotoxicity with conazole fungicides and find an overall good correlation with results from animal studies and Barae Jomaa et al. challenge *in vitro* thyroid and pituitary cell proliferation assays with thyroid-active compounds and compare their results with results from animal studies. They find that the current *in vitro* assays do not cover all relevant modes of action and recommend the development of further *in vitro* assays, but they find that the tests may be helpful to predict *in vivo* effects on relative heart weight. Sebastian Polak harnesses two *in silico* platforms for pharmacokinetics prediction and cardiac effect prediction to model the *in vivo* effects of quinidine on humans based on *in vitro* data. He demonstrates that this prediction correlates well with data from clinical studies on the drugs' effects and may be suitable for application as a drug safety evaluation procedure.

A workshop report, five corners, and more current news round off this issue.

Wishing you a good summer break and a productive meeting in Linz this September,

Sonja von Aulock
Editor in chief, ALTEX



International Conference on
Alternatives to Animal Models



**HRDF
Claimable**
*subject to approval
CPD Points
will be awarded



Date : 3 - 4 October 2013
(Thursday and Friday)
Time : 8.00 am - 5.00 pm
Venue : IMU Bukit Jalil,
Kuala Lumpur,
Malaysia

INTERNATIONAL CONFERENCE ON ALTERNATIVES TO ANIMAL MODELS: New Trends and Current Progress

Theme: Addressing the needs of 3Rs: Issues and Challenges

Keynote Speakers



Prof Thomas Hartung
Johns Hopkins Bloomberg School of Public
Health, Baltimore, USA
Topic: *Current International Progress on
Alternative Animal Model Development*



Prof David Dewhurst
University of Edinburgh, Edinburgh, United
Kingdom
Topic: *Implementation of Alternatives into
Medical Education and Training*

Other Speakers

Asst Prof Madhavan Nallani,
Nanyang Technological University, Singapore
Topic: *Bioengineering and Synthetic
Membranes: Answer to Alternatives*

Asst Prof Chen Nanguang,
National University of Singapore, Singapore
Topic: *Small Animal Non-Invasive Imaging Techniques*

Assoc Prof Alexander Chong Shu Chien,
University Sains Malaysia, Malaysia
Topic: *Alternative Non-Mammalian Models for Diseases and
Drug Discovery: Tales From a Fish and a Worm*

Associate Prof Sandy Loh Hwei San,
University of Nottingham, Kuala Lumpur Campus, Malaysia
Topic: *Plant Based Vaccine Production*

Assoc Prof Leong Chee Onn,
International Medical University, Malaysia
Topic: *Recent Advances in Vitro Cell Culture Techniques*

Assoc Prof Eric Chan Chun Yong,
National University of Singapore, Singapore
Topic: *Metabolomics in Toxicity Testing*

Assoc Prof Wannapong Triampo,
Mahidol University, Thailand
Topic: *Computer Simulation and Mathematical Modelling*

The International Conference on Alternatives to Animal Models (ICAAM 2013) is a platform to exchange ideas, experiences, to showcase innovations and to forge and renew a mutual understanding between international researchers of various professions from the region and beyond in the field of alternatives to animal testing. This prestigious conference is organised by the International Medical University and will be held in Kuala Lumpur, Malaysia during the 3rd and 4th of October, 2013.

Poster Presentation

Call for Abstracts

Deadline for abstract submission is on 23 August 2013. Please visit www.imu.edu.my/icaam

Travel Grants

Three best posters will receive travel grants worth RM1000 each.

Highlights

- Promoting and propagating the concept of the 'Three Rs' in animal testing
- Exploring the current international developments in the 'Three Rs'
- Linking the 'Three Rs' to animal welfare
- Emerging science and the potential for replacement in biomedical research
- Alternatives to using animals in teaching and training
- Promoting the alternative methods all over the world
- Bridging the distance between science and policy and identifying opportunities for collaborations
- Business opportunities and priority setting in alternative research
- Keynote addresses by Prof. Thomas Hartung and Prof. David Dewhurst

Target Audience

- Researchers
- Academicians
- Veterinarians
- Animal Welfare Organisation Members
- Public Representatives
- Healthcare Professionals

Registration Fee

	Regular	Early Bird (By 31/07/2013)
Malaysian	RM1,500	RM1,050
International	USD525	USD375

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International Conference On Alternatives To Animal Models (ICAAM)

International Medical University
126, Jalan Jalil Perkasa 19, Bukit Jalil,
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