DIA WORKSHOP ON
BIOMARKERS IN THE DRUG DEVELOPMENT PROCESS
NOVEMBER 21-22, 2007, HOTEL NH BARBIZON PALACE, AMSTERDAM,
THE NETHERLANDS

PROGRAMME CHAIRPERSON
BERT HAENEN, Toxicologist, Organon Biosciences, The Netherlands

PROGRAMME COMMITTEE
KLAUS OLEJNICZAK, Head of Biochemical Toxicology, BfArM, Germany
PER SPINDLER, Director, BioLogue/Danish Pharma Consortium, Denmark
GERD BODE, Consultant and Lecturer at the University of Göttingen,
Germany
KENNETH HASTINGS, Associate Director for Pharmacology and
Toxicology, CDER, FDA, USA

WORKSHOP OVERVIEW
The pharmaceutical and clinical diagnostic industry, as well as research
groups at hospital universities, are continuously searching for novel biomark-
ers of disease states, drug-response, drug efficacy and drug toxicity.

At this workshop, systems biology, (toxico)genomic, functional genomic,
proteomic and metabonomic data related to biomarker development will be
presented and discussed among academia, industry and regulators. The syn-
ergistic path of discovery and development of biomarkers during the drug
development process will be presented and discussed.

Presentations will also include examples of organ specific safety biomarkers:
challenges in discovery, development and registration, as well as for clinical
efficacy biomarkers in different biological fluids. A special presentation has
been added on the latest developments in the use of epigenetics for cancer
therapy.

In the workshop an update will be provided on the US C-Path Initiative
(www.c-path.org) and on the European Innovative Medicines Initiative
(www.imi-europe.org). The US and European regulatory view on acceptance
of novel biomarkers will be presented and discussed by a panel.

Although the Workshop focuses on the discovery of novel biomarkers using
"omics" techniques, their need will also be critically reviewed. The work-
shop set-up will enable interactive (group) discussions on contemporary
industry, academic and regulatory challenges in biomarker development and
the systems in which they are embedded.
Tuesday, November 20, 2007

18:00-20:00
Pre-Registration
Pick up your badge and conference materials early to avoid queues!

Wednesday, November 21, 2007

07:15-08:15
Registration & Welcome Coffee

08:15
Welcome and Opening Remarks
Programme Chairperson: Bert Haenen, Organon Biosciences, The Netherlands

08:30
Session 1
OVERVIEW OF BIOMARKER APPROACHES
Session Chairperson: Bert Haenen, Organon Biosciences, The Netherlands
Introduction
Bert Haenen, Organon Biosciences, The Netherlands
Biomarker Approaches for Enhancing Drug Discovery and Development
Alain van Gool, Organon Biosciences, The Netherlands
The Necessity of Novel Biomarkers: What’s Wrong with the Classical Clinical Pathology Data?
Speaker to be confirmed

09:45
Session 2
BIOMARKER INITIATIVES IN THE US AND EUROPE
Session Chairperson: Per Spindler, BioLogue/Danish Pharma Consortium, Denmark
Update on EU Innovative Medicines Initiative
Per Spindler, BioLogue/Danish Pharma Consortium, Denmark
Update on FDA’s Critical Path Initiative: Nephrotox + Vascular Injury
William B. Mattes, Critical Path Institute, Rockville, USA

10:45
Coffee Break

11:15
Session 3
TOXICOGENOMICS AND PROTEOMICS
Session Chairperson: Anja Hviid Simonsen, Bio-Rad Laboratories, Denmark
Use of Toxicogenomics to Detect Hepatotoxicants
Arno Kalkuhl, Boehringer Ingelheim Pharma, Germany
Mechanism-Based Toxicogenomics for Cancer Hazard Assessment of (Non)-Genotoxic Chemicals
Bob van de Water, LACDR Leiden, The Netherlands
Biomarker Discovery in Biological Fluids
Anja Hviid Simonsen, Bio-Rad Laboratories, Denmark

14:00
Session 4
REGULATORY ACCEPTANCE OF “OMICS” DATA
Session Chairperson: Klaus Olejnizcak, BfArM, Germany
Regulatory Acceptance of Safety “omics” Data:
FDA Point of View
Kenneth Hastings, FDA, USA
EMEA Point of View
Connie Brouwer, RIVM, The Netherlands
Biomarker Approaches in Regulatory Discussions
Klaus Olejnizcak, BfArM, Germany

15:30
Coffee Break

16:00
Session 5
ORGAN SPECIFIC BIOMARKERS I
Session Chairperson: Malcolm York, GlaxoSmithKline, UK
Biomarkers of Drug-Induced Cardiac Toxicity
Malcolm York, GlaxoSmithKline, UK
Evaluation of Novel Biomarkers of Nephrotoxicity (ILSI/HESI Initiative)
Ernie Harpur, sanofi-aventis, UK
Depression and Biomarkers
Birgitte Søgaard, H. Lundbeck A/S, Denmark

17:30
End of Day 1

20.00
Working Dinner (optional)

22:30
Thursday, November 22, 2007

08:30
Session 6
PLENARY DISCUSSION ON OUTCOME OF GROUP DISCUSSIONS
Session Chairperson: Alain van Gool, Organon Biosciences, The Netherlands

10:00
Coffee Break

10:30
Session 7
ORGAN SPECIFIC BIOMARKERS II
Session Chairperson: Gerd Bode, Consultant, Germany
Semi-Automated Systems for Organ Specific Toxicity Screening in Metabonomics: the COMET Approach
Tim Ebbels, SORA Division, Imperial College London, UK
Biomarkers for Liver Toxicity?
Gerd Bode, Consultant, Germany
Discussion

12:00
Lunch Break
13:30  Session 8

BIOMARKERS IN THE CLINIC

Session Chairperson: Kenneth Hastings, FDA, USA

CSF Proteome as Potential Source for Identification of Biomarkers for Migraine
Floor Bakels, Leiden University Medical Center, The Netherlands

From Bench to Bedside: Development and Clinical Use of Microarray-Based Diagnostic Tests
Iris Simon, Agendia B.V., The Netherlands

Clinical Biomarkers in Clinical POC Studies in the Respiratory/Inflammation Disease Areas (tbc)
Speaker to be confirmed

15:00  Coffee Break

15:30  Session 9

FUNCTIONAL GENOMICS AND EPIGENETICS

Session Chairperson: Manon van Engeland, University of Maastricht, The Netherlands

A New Paradigm in Toxicology and Drug Safety: Targeting the Epigenome
Jürgen Borlak, Fraunhofer Institute of Toxicology and Experimental Medicine, Germany

Epigenetic Cancer Therapy: Nonclinical and Clinical Experience
Manon van Engeland, University of Maastricht, The Netherlands

16:30  Wrap-up and Close of Meeting

Programme Chairperson: Bert Haenen, Organon Biosciences, The Netherlands

16:45  End of Workshop

Hotel Information

The DIA has blocked a number of rooms at the:

Hotel NH Barbizon Palace Amsterdam
Prins Hendrikkade 59-72, NL-1012 AD Amsterdam, The Netherlands
Tel: +31 (0)20 556 4564
Fax: +31 (0)20 624 3353
Email: nhbarbizonpalace@nh-hotels.com
www.nh-hotels.com

at the special rate of:

Single Room  EUR 189.00
Breakfast  EUR 26.00

The rate is per room and night (single use), including service and VAT, excluding breakfast and city tax (5%).

In the centre of Amsterdam, in front of the central railway station, the NH Barbizon Palace Amsterdam is conveniently located close to the shopping, business and leisure areas. The hotel is a 20-minute drive away from Amsterdam Schiphol International Airport.

IMPORTANT:
To be assured of accommodation at the Hotel NH Barbizon Palace Amsterdam, registrants are recommended to complete their reservation by October 10, 2007.

ACCOMMODATION BOOKING FORM
1 FORM PER RESERVATION

DIA WS07106 - November 21-22, 2007
DIA Workshop on Biomarkers in the Drug Development Process
Please fax completed form to the Hotel NH Barbizon Palace Amsterdam by October 10, 2007

Hotel NH Barbizon Palace Amsterdam
Prins Hendrikkade 59-72, NL-1012 AD Amsterdam, The Netherlands
Tel: +31 (0)20 556 4564
Fax: +31 (0)20 624 3353
Email: nhbarbizonpalace@nh-hotels.com

Guest

Prof.  Dr.  Ms.  Mr.

Last Name
First Name & Middle Initial
Company
Job Title
Street Address / P.O. Box

Postal Code
City
Country
Telephone
Telefax
E-Mail

Room  Single EUR 189.00

The above rate is per room per night, inclusive service and VAT, excluding breakfast and city tax (5%).

☑ non smoking  ☐ smoking

Arrival date: Expected Time of Arrival:
Departure Date: Number of Nights:

In case of cancellation: Cancellation must be in writing. One night deposit will be kept as cancellation fee. All no shows will be billed for the entire stay.

Payment

☑ I hereby authorize the NH Barbizon Palace Amsterdam to charge my credit card according to the conditions mentioned above.

Visa  MC  AMEX  Diners  Other: _______________________

Card Number
Exp.date
Cardholder’s Name
Date
Cardholder’s signature
## Registration Form - I.D. Code # 07106

### DIA Workshop on Biomarkers in the Drug Development Process

**November 21-22, 2007 - Hotel NH Barbizon Palace, Amsterdam, The Netherlands**

**MEMBERSHIP**
- **€ 130.00**

Join DIA now to save on meeting registration fees, and to receive all the benefits of membership for a full year!!

A one-year membership to DIA is available to those paying a NON-MEMBER meeting registration fee. Your choice of nonmember fee will indicate if you DO or DO NOT, wish to become a member.

### Early-Bird Deadline
- **ON OR BEFORE OCTOBER 10, 2007**
- **€1’100.00**

### Registration Fees

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<th>Member (with optional membership)</th>
<th>Non-Member (without optional membership)</th>
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### Please Indicate the Total Amount to Be Paid:

**€**

Note: Payment of registration fees must be received before commencement of the meeting.

### Group Discount Available! Send 3, the 4th is FREE

Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must be registered and prepay at the same time.**

DIA will apply the value of the lowest applicable fee to this complimentary registration. It does NOT include fees for optional events or DIA membership. Substitutions of enrolled delegates of similar membership may be made at any time. Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company and return them together to DIA.

- Please indicate that this form is part of a group registration by ticking this box. Please indicate the full names of the other three registrants from your company.

2. Name
3. Name
4. Name

### REGISTRANT
- [ ] Prof.
- [ ] Dr.
- [ ] Ms.
- [ ] Mr.

- **Last Name**
- **First Name**
- **Company**
- **Job Title**
- **Street Address / P.O. Box**
- **Postal Code**
- **City**
- **Country**
- **Telephone**
- **Telefax (Required for confirmation)**
- **Email (Required for confirmation)**

### Payment Methods
- [ ] Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.
- [ ] VISA
- [ ] MC
- [ ] AMEX

- **Card Number**
- **Exp. Date**
- **Cardholder’s Name**
- **Date**
- **Cardholder’s Signature**

### Cheques
- Should be made payable to: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, Elisabethenanlage 11, Postfach, 4002 Basel, Switzerland.

### Bank Transfers
- When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be in EURO and your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your DIA account.

### Workshop Cancellation Policy

All cancellations must be in writing and be received at the DIA office by 17:00 on November 14, 2007. Cancellations received in writing on or before November 14, 2007 – Administrative fee that will be deducted from fee paid: Full Meeting Cancellation: Member/Non-member = EUR 200.00 Government/Academia/Nonprofit (Member/Non-member) = EUR 100.00 Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own airline and hotel reservations. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for non-member fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Persons under 18 are not allowed to attend DIA meetings.

### Hotel and Travel Reservations

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation letter via fax within five working days, please contact the DIA Basel Office.

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