

Personalised Medicine

- **Stratification biomarkers in personalised medicine**
 - **From early development to market**

**DGRA-Workshop for members
on April 5th, 2011
at Wissenschaftszentrum Bonn,
Ahrstraße 45, 53175 Bonn, Germany**

10:00 a.m. - ca. 5:00 p.m.

Moderator: Dr. Christine Mayer-Nicolai

Speakers: Dr. Karl Broich, BfArM Federal Institute for Drugs and Medical Devices
Prof. Dr. Ilhan Celik, Merck Serono
Prof. Dr. Bruno Flamion, University of Namur Belgium
Dr. Marc Maliepaard, MEB The Netherlands Medicines Evaluation Board Agency
Dr. Jean-Luc Sanne, European Commission
Dr. Harpreet Singh, immatics biotechnologies GmbH

Programme:

10.00 a.m. I. Personalised Medicine: How can the innovative potential be leveraged?

- Limitations and chances
- Can PM create biomedical R&D leadership for Europe to benefit patients and society?

Dr. Jean-Luc Sanne, European Commission

10.45 a.m. Coffee break

11.15 a.m. II. PGx in early drug development – Status of implementation for PK

- Draft EMA Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products

Dr. Marc Maliepaard, MEB

11.45 a.m. III. Regulatory acceptance of new technologies and biomarkers in development and registration of new medicines

- Using new biomarkers in drug development enrichment vs stratification
- Qualification of “New Methodologies” at the EMA: a parallel EMA/FDA procedure

Prof. Dr. Bruno Flamion, University of Namur

12.30 p.m. Lunch break

1.30 p.m. IV. The future role of biomarkers in personalised medicine: current developments at EMA and FDA

- Different roles of biomarkers in drug development
- Qualification process for biomarkers at EMA
- Requirements on biomarkers for surrogacy

Dr. Karl Broich, BfArM

2.15 p.m. V. Genomics in personalised medicine – targeting the right patient

Prof. Dr. Ilhan Celik, Head of Biomarker Strategy Oncology, Merck Serono

3.00 p.m. Coffee break

3.30 p.m. VI. Biomarker-based personalization of cancer immunotherapy – opportunities and challenges“.

Dr. Harpreet Singh, immatics biotechnologies GmbH

4.15 p.m. VII. Concluding discussion of the panel

all speakers and participations

ca. 5.00 p.m. End

(Program subject to change without prior notice.)

Informations and Organisational References

p.t.o.

Date:

Tuesday, April 5th 2011
Start: 10.00 a.m.
End: around 5.00 p.m.

Venue:

Wissenschaftszentrum Bonn, Ahrstraße 45,
D-53175 Bonn, phone: 0228/302-0

Participation fees:

For DGRA members and M.D.R.A. students
course XII: € 240

(The Casino is open for lunch (not included))

Cancellation terms:

Up to two weeks before the first day of the
conference(22-March-11): € 50; up to one week
before the first day of the conference (29-March-
11): 50% of fee; late cancellations: full
conference fee if a substitute participant (DGRA
member) cannot be put forward.

In the event of cancellation by the organizer, any
fees already paid will be fully reimbursed.

Conference language:

English

Room reservation:

A limited number of rooms are available for
participants at special rates in the hotels listed
below. When making reservations(up to 4 weeks
before the workshop) please refer to DGRA.

- Hotel Königshof, Bonn-Innenstadt
Phone: 0049- 228/26010
- Hotel Maritim, Bonn
Phone.: 0049 – 228/ 8108-0
- Hotel Residence, Bonn-Innenstadt
Phone: 0049 - 228/2697703

More available rooms for direct booking
www.bonnhotels.de (incl. public transport),
www.hrs.de

Registration:

DGRA members are requested to use the form at
www.dgra.de or contact us at info@dgra.de

DGRA-office

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