

WEDNESDAY, APRIL 29, 2009

Session 3: Managing the risk of Phase I trials

Chair: Y. Donazzolo, Grenoble; K. Breithaupt-Grögler, Frankfurt/M

08:45 Identification and mitigation of risks in first-in-human clinical trials - pitfalls and challenges of a unified process within a worldwide CRO
M. Grossmann, Berlin

Usefulness of MABEL concepts
B. Laurijssens, London

Accreditation of phase I units in the UK
J. Täubel, London

Accreditation of phase I units in France
A. Patat, Rennes

Accreditation of phase I units in Germany
T. Thomsen, Andernach

10:30 Coffee Break

11:00 Parallel workshops

7) Monoclonal antibodies in or out of oncology.
G. Salles, Lyon; N. Franchimont, Zug

8) Society for Pharmaceutical Medicine workshop: MABEL Concept
D. Jones, London; B. Laurijssens, London

9) Personalized medicine / theragnostics.
M. Zühlsdorf, Cologne

10) Informed consent in pharmacogenomics / individualized medicine – responses from various ethics committees within the EU.
M. Könen-Bergmann, Ingelheim

12) Exploratory trials workshop
Y. Donazzolo, Grenoble; D. Tremblay, Paris

11) BAPU workshop: What is a healthy volunteer?
D. van der Mijnsbrugge, Antwerp;
S. Ramael, Brussels

12:30 Lunch Break

Session 4: Safety concerns in early development

Chair: I. Paty, Paris; H. Fuder, Hamburg

13:30 Stopping criteria in first-in-man studies
A. Patat, Rennes, M. Sibille, Lyon

Serious adverse event registry
M. Sibille, Lyon, C. Hinze, Rheinau

Lessons learned from thorough QTc studies performed by a pharmaceutical company
H. Caplain, Paris

New approaches for the assessment of drug abuse liability
J.-L. Pinquier, Paris

15:45 **Closing Remarks**
A. Patat, Rennes

16:00 **End of Meeting**

Conference fees:

- **Regular fees after 1 January 2009:**
325,00 € members*
375,00 € non-members
200,00 € day ticket

*) Members of AGAH, CPI, AHPPI, BAPU, and SPM

Online registration and hotel reservation:

Please use the link to the Kuoni registration form at www.clubphase1.fr or www.agah-web.de



3rd Joint Annual Meeting

MANAGING CHALLENGES IN EARLY DRUG DEVELOPMENT: BIOLOGICALS AND SMALL MOLECULES



APRIL 28 & 29, 2009
ESPACE TETE D'OR, LYON, FRANCE

MANAGING CHALLENGES IN EARLY DRUG DEVELOPMENT

Biologics and small molecules are a challenging experience and expectations as to their potential are high. However, the first administration of a new compound to man is a particularly critical moment in drug development, pre-clinical information is limited and not necessarily transferable to humans. New molecules with not yet fully understood pharmacological action can yield unpredictable outcomes of otherwise well designed trials.

This meeting will address how sponsors, investigators, regulatory authorities and ethics committees are adapting to these new challenges. It is already the third Joint Meeting of AGAH and Club Phase 1 and we are delighted to also welcome our colleagues from Belgium and the UK.

TUESDAY, APRIL 28, 2009

08:30 Registration

09:00 Opening Remarks
*A. Patat, Rennes; M. Sibille, Lyon;
T. Thomsen, Andernach*

Session 1: New biological entities and vaccines

Chair: H. Caplain, Paris; J.-F. Nicolas, Lyon

09:15 New targets – new vaccines
J.-F. Nicolas, Lyon

Early development plan for a vaccine
R. Forrat, Lyon

Development of new biological entities
J.-Y. Bonnefoy, Strasbourg

10:45 Coffee Break

11:15 Parallel workshops

1) Update on the design of studies of drug-drug interaction with special focus on transporters
D. Chassard, Paris; J.-M. Scherrmann, Paris

2) Human pharmacology's contribution to the preparation of paediatric development plans
I. Klingmann, Brussels; W. Seifert, Berlin

3) Critical appraisal of studies with elderly in early development
C. Reh, Berlin

4) Determination of antibodies following administration of small proteins
I. Paty, Paris; F. Bérard, Lyon; P. Cortez, Montpellier

5) What to expect from Holter ECGs in early development?
P. Voiriot, Nancy

6) AHPPI workshop:
Translational medicine – dream or nightmare?
P. Dewland, Llanyre; T.Mant, London

12:45 Lunch Break

Session 2: Current European experience with trial approval in early development

Chair: I. Klingmann, Brussels; A. Patat, Rennes

14:00 AFSAPPS: Data on timelines, missing aspects in dossiers, reasons for delays, questions to applicants, how to improve the process
C. Belorgey, Paris

BfArM / PEI: Data on timelines, missing aspects in dossiers, reasons for delays, questions to applicants, how to improve the process
T. Sudhop, Bonn

Belgium: Data on timelines, missing aspects in dossiers, reasons for delays, questions to applicants, how to improve the process
W. Janssens, Brussels

UK: Data on timelines, missing aspects in dossiers, reasons for delays, questions to applicants, how to improve the process
J. Ward, London

15:30 Coffee Break

Differences in responses from Ethics Committees to clinical trial applications in France
F. Chapuis, Lyon

Differences in responses from Ethics Committees to clinical trial applications in the UK
M. Bone, Newcastle

Differences in responses from Ethics Committees to clinical trial applications in the Netherlands
R. A. de Zeeuw, Assen

Applicants perspective on data from the approval process between 2004 and 2008
T. Ruppert, Berlin

17:00 Round table discussion on trial approval in early drug development

All speakers of the afternoon session
Introduction: ICREL results on trial approval
I. Klingmann, Brussels

17:45 **End of Session**

19:30 **Conference Dinner**