

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](http://www.clubphase1.fr) or [www.agah-web.de](http://www.agah-web.de)



3<sup>rd</sup> 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*

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### 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

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### 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**