Preliminary Program

As of: April 11, 2012

Scientific Committee

Co-chairpersons:
Paul-Henri Lambert, University of Geneva, Switzerland
William Egan, Novartis
Ian Gust, University of Melbourne
Rebecca Sheets, NIH/NIAID

07:30	**Registration**
08:00	**Continental breakfast**
08:45	**Opening** ***Johannes Löwer***, *President*, *IABS* ***Paul-Henri Lambert***, *University of Geneva*

Day 1 - Thursday, May 10, 2012

Session I
Molecular monitoring of vaccine reactogenicity in the context of regulatory processes

Chairperson: ***William Egan,*** *Novartis*

09:00 - 09:30	Understanding inflammation ***Eicke Latz,*** *University of Bonn, Germany & University of Massachusetts*
09:30 - 09:40	Discussion
09:40 - 10:00	Present assessment of local and systemic vaccine reactogenicity ***Jeffrey Roberts,*** *FDA/CBER/OVRR, USA*
10:00 - 10:10	Discussion
10:10 - 10:30	Quality control: *in vitro* assessment of vaccines by monocyte activation test (MAT) ***Ingo Spreitzer,*** *Paul-Ehrlich-Institut, Langen, Germany*

10:30 - 10:40 Discussion

10:40 - 11:00 Coffee Break

11:00 - 11:20 Early immunological events triggered by the vaccine adjuvant MF59 in mice
***Ennio De Gregorio**, Novartis, Siena, Italy*

11:20 - 11:30 Discussion

11:30 - 11:50 Developing a vaccine safety classifier in non-human primates
***I-Ming Wang**, Merck Research Laboratories, West Point, PA, USA*

11:50 - 12:00 Discussion

12:00 - 12:20 Exploring inflammasome and adjuvanticity in clinical studies
***Alessandra Mortellaro,** Singapore Immunology Network (SIgN)*

12:20 - 12:30 Discussion

12:30 Lunch

14:00 - 14:50 **Panel Discussion**
***Chairperson: Norman Baylor**, Biologics Consulting Group, Inc. Alexandria, VA, USA*

Which biomarkers should be considered for measuring vaccine-induced inflammation at local and systemic level?

- Which biomarkers can be used in early clinical trials?
- Validation process?
- Views of regulators & industry

Panelists: **Ingo Spreitzer**, PEI; **Ennio De Gregorio**, Novartis; **I-Ming Wang**, Merck Research Lab.; **Arnaud Didierlaurent,** GSK Biologicals; **Alessandra Mortellaro**, Singapore Immunology Network; **Jeffrey Roberts**, FDA/CBER/OVRR

Session II
Monitoring of vaccine-induced innate immunity in the context of regulatory processes

*Chairperson: **Ian Gust,** University of Melbourne, Australia*

14:55 - 15:35 **Keynote lecture**
Biomarkers of innate immunity following vaccination: towards systems vaccinology
***Bali Pulendran**, Emory University, Atlanta, GA, USA*

15:35 - 15:45 Discussion

15:45 - 16:05 Coffee Break

In vitro approaches

16:05 - 16:25 Use of in-vitro models of the human immune system to assess adjuvanted vaccines
***William Warren**, VaxDesign Campus, Sanofi Pasteur, Orlando, FL, USA*

16:25 - 16:35 Discussion

16:35 - 16:55 **Animal models**
Influence of vaccine formulations and mode of administration on the kinetics and breadth of APC targeting in the draining lymph nodes
Claire-Anne Siegrist, *University of Geneva, Switzerland*

16:55 - 17:05 Discussion

17:05 - 17:25 Assessing innate immunity induced by adjuvant systems
Arnaud Didierlaurent*, GSK Biologicals, Rixensart, Belgium*

17:25 - 17:35 Discussion

Day 2 - Friday, May 11, 2012

Session II (continued)
Monitoring of vaccine-induced innate immunity in the context of regulatory processes

08:00 **Continental breakfast**

09:00 - 09:20 Clinical Studies

Scientific investigations of trivalent influenza vaccine-induced adverse events in the paediatric population: role of innate immunity
Eugene Maraskovsky, *CSL, Parkville, Australia*

09:20 - 09:30 Discussion

09:30 - 09:50 Gene expression profiles following live and inactivated influenza vaccines
Wei Zhu*, MedImmune, Gaithersburg, MD, USA*

09:50 - 10:00 Discussion

10:00 - 10:20 **Break**

10:20 - 11:20 **Panel Discussion**
Chairperson: Robert L. Coffman*, Dynavax Technologies, Berkeley, CA, USA*
Should innate immunity be assessed in early vaccine trials in the context of regulatory processes?

- Can biomarkers be used for comparative adjuvant /formulation assessment?
- Can biomarkers be used to compare vaccine and natural infection?
- Relative importance of in-vitro and in-vivo preclinical assays.

Panelists: **Pieter Neels**, EMA; **Hana Golding**, FDA; **William Warren**, Sanofi Pasteur; **Nathalie Garçon**, GSK Biologicals

Session III
Monitoring of vaccine effects on unrelated immune responses

Chairperson: ***Rebecca Sheets,*** *NIH/NID*

11:25 - 11:45 Assessing innate immunity effects in animal models of autoimmune diseases
Willem van Eden*, Utrecht University, The Netherlands*

11:45 - 11:55 Discussion

12:00 - 13:30 Lunch

13:30 - 13:50 Can one predict the effects of vaccination in atopic patients?
Patrick Holt*, Telethon Institute for Child Health Research, Perth, Australia*

13:50 - 14:00 Discussion

14:00 - 14:20 Assessing bystander immunological activation following vaccination in humans
Gianfranco Di Genova*, University of Southampton, UK*

14:20 - 14:30 Discussion

14:30 - 15:00 Can one predict a high risk of autoimmune disease before vaccination?
George Eisenbarth*, Barbara Davis Center, University of Colorado, Denver, CO, USA*

15:00 - 15:10 Discussion

15:10 - 15:30 **Panel Discussion on non-specific immunological effects**
Chairperson: Michel Goldman*, IMI, Brussels*

- Should early atopy or autoimmune disease risk biomarkers be used in early clinical trials?
- Should immunological interferences be monitored at pre-clinical or early clinical stages of vaccine development?

Panelists: **William Warren**, Sanofi Pasteur; **Willem van Eden**, Utrecht University; **Patrick Holt**, Telethon Institute for Child Health Research; **Gianfranco Di Genova**, University of Southampton; **George Eisenbarth**, University of Colorado; **Norman Baylor**, BCG, Inc.; **Pieter Neels**, EMA

15 :30-15 :50 Key conclusions of the meeting
David Lewis*, University of Surrey, UK*

15:50 - 16:00 **Concluding Remarks**
William Egan, *Novartis*