

VACCINES AND ADJUVANTS SAFETY PROJECT COMMITTEE

Mission

The mission of the Project Committee on Vaccines and Adjuvants Safety is to establish and bring together the collective knowledge of scientists from academia, industry, and government, to better understand adjuvant and vaccine safety, with a focus on autoimmunity, to provide a rigorous approach in how to move forward in the development of adjuvants, and ultimately to help minimize serious adverse events associated with adjuvants in vaccines.

2012-2013 Participating Organizations

Austrian Agency for Health and Food Safety

Cornell University

French Agency for the Safety of Health Products

GlaxoSmithKline

Janssen Pharmaceuticals

Medicines Evaluation Board (The Netherlands)

MedImmune

National Institute of Biomedical Innovation (Japan)

Novartis Pharmaceuticals

Osaka University

Pfizer Inc.

Pharmaceuticals and Medical Devices Agency (Japan)

Sanofi

Takeda Pharmaceutical Company, Limited

US Food and Drug Administration

2012-2013 Activities and Accomplishments

Committee leaders:

Dr. Sarah Gould
Sanofi

Dr. Jan Willem
van der Laan
Medicines Evaluation
Board

HESI manager:

Dr. Jennifer Young Tanir



This scientific program is committed to:

Establishing the collective knowledge of scientists from academia, industry, and government to better understand the relationship between adjuvants and vaccine safety, with a focus on autoimmunity.

Areas of scientific focus:

- Animal models and biomarkers to assess the potential for association between autoimmunity and adjuvants.
- Adjuvants consisting of mineral oils, emulsions, or squalene.
- Adjuvants targeting Toll-like receptor agonists.

Why get involved?

- Engage in discussions with international experts and in a literature analysis to better understand a possible association between autoimmunity and adjuvants in vaccines.
- Contribute toward understanding the long-term safety of adjuvants and provide data of value in addressing concern about the use of adjuvants in vaccines.

Key accomplishments:

- *Literature Survey.* The committee, which was initiated in 2011, divided into three subgroups, one on each area of scientific focus, and conducted a comprehensive literature survey and analysis to identify the key issues and to shape the focus of a 2012 workshop.
- *Workshop.* On October 18–19, 2012, the committee held the “Workshop on Adjuvants and Vaccines: Focus on Autoimmunity,” in Amsterdam, The Netherlands. This workshop brought together the collective knowledge of scientists from academia, industry, and government to better understand the relationship between adjuvants and vaccine safety, with a focus on autoimmunity. The purpose of the workshop was to assess the state of current knowledge with regard to the potential association between adjuvants and autoimmune responses, pool data and insights across studies and literature including *in vitro*, animal, and human data, discuss key questions, and develop recommendations for future evaluation. The workshop was highly interactive, with numerous open discussions during the sessions and positive feedback post-workshop. This has provided the committee with a good insight into the latest science relating to this topic, which will be reflected in the publication.

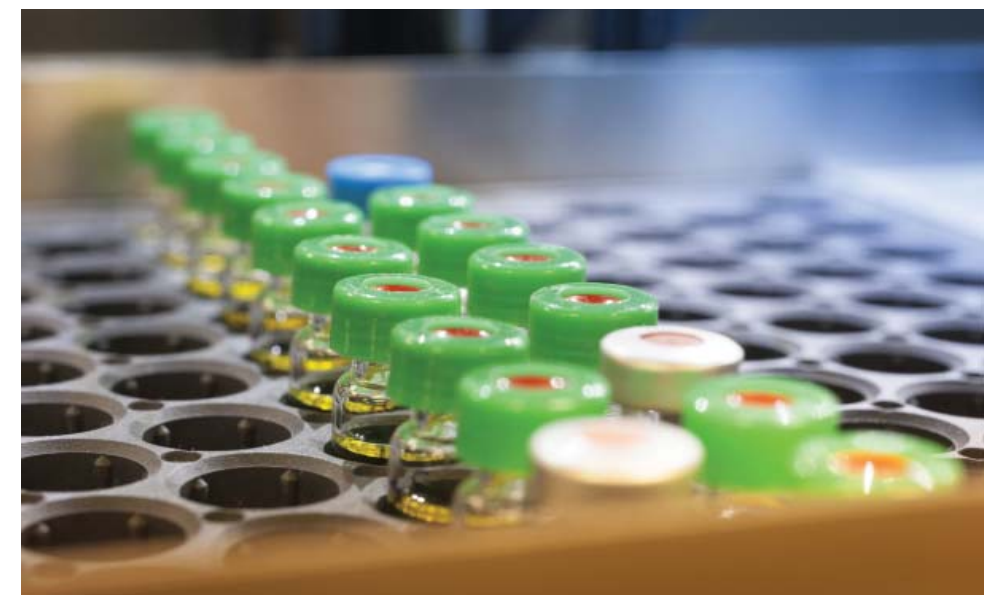
The Committee's focus for May 2013 - May 2014:

- The committee will publish a manuscript describing the findings and recommendations of the committee resulting from the workshop on the potential relationship between adjuvants in vaccines and autoimmunity.
- The conclusions will be communicated to the scientific community through presentations at meetings and conferences.
- Future activities of the committee will be more clearly defined in a workplan.

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Cornell University
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Sanofi
Takeda Pharmaceuticals
US Food and Drug Administration

For more information, contact the Committee's manager, Dr. Jennifer Young Tanir, jtanir@hesiglobal.org.



Vaccines and Adjuvants Project Committee Event

October 18-19, 2012: HESI Workshop on "Adjuvants and Vaccines: Focus on Autoimmunity" Sponsored by the HESI Vaccines and Adjuvants Safety Project Committee. Amsterdam, The Netherlands.

WORKSHOP OVERVIEW

This workshop, organized by the HESI Vaccines and Adjuvants Safety Project Committee, will bring together the collective knowledge of scientists from academia, industry, and government to better understand the relationship between adjuvants and vaccine safety, with a focus on autoimmunity. The purpose of the workshop is to assess the state of current knowledge with regard to the potential association between adjuvants and autoimmune responses, pool data and insights across available literature including in vitro, animal, and human data, discuss key questions, and develop recommendations for future evaluation.

PROGRAM COMMITTEE

Sarah Gould, Sanofi-Pasteur, France

Heather Davis, Pfizer, Canada

Rodney Dietert, Cornell University, USA

Deborah Novicki, Novartis Vaccines and Diagnostics Toxicology, USA

Jan Willem van der Laan, Medicines Evaluation Board, The Netherlands

Jennifer Young, Scientific Program Manager, HESI, USA



Workshop on Adjuvants and Vaccines: Focus on Autoimmunity



18-19 October 2012

Doubletree by Hilton Hotel Amsterdam
Centraal Station, Amsterdam, The Netherlands

PURPOSE OF WORKSHOP

This workshop, organized by the HESI Vaccines and Adjuvants Safety Project Committee, will bring together the collective knowledge of scientists from academia, industry, and government to better understand the relationship between adjuvants and vaccine safety, with a focus on autoimmunity. The purpose of the workshop is to assess the state of current knowledge with regard to the potential association between adjuvants and autoimmune responses, pool data and insights across available literature including *in vitro*, animal, and human data, discuss key questions, and develop recommendations for future evaluation.

BACKGROUND OF HESI VACCINES & ADJUVANTS SAFETY PROJECT COMMITTEE

This scientific program, initiated in 2011, is committed to establishing and bringing together the collective knowledge of scientists from academia, industry, and government, to better understand adjuvant and vaccine safety, with a focus on autoimmunity, to provide a rigorous approach in how to move forward in the development of adjuvants, contribute toward understanding the long-term safety of adjuvants, and provide data of value in addressing concern about the use of adjuvants in vaccines.

The areas of scientific focus, which are the focus of this workshop, are:

- Adjuvants consisting of oil-in-water emulsions
- Adjuvants targeting Toll-like Receptor (TLR) agonists
- Animal models and biomarkers for associating autoimmunity with adjuvants

The Committee has identified the key issues based on analysis of the literature and input from academic, industrial and governmental experts. During this workshop, participants will discuss in depth the key issues identified during the literature survey and publish the resulting working hypotheses and recommendations for further research.

PROGRAM COMMITTEE

Dr. David Clarke, Pfizer, USA

Dr. Heather Davis, Pfizer, Canada

Dr. Rodney Dietert, Cornell University, USA

Dr. Sarah Gould, Sanofi, France

Dr. Deborah Novicki, Novartis, USA

Dr. Jan Willem van der Laan, Medicines Evaluation Board, The Netherlands

Dr. Jennifer Young, ILSI Health and Environmental Sciences Institute, USA

Additional support for the workshop provided by the HESI Immunotoxicology Technical Committee.

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(HESI) email: JYoung@ilsi.org; telephone: +1 202 659 3306 x132

Workshop website: <http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3599>
Project Committee website: <http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3585>

FINAL PROGRAM

(Updated 15 October 2012)

WORKSHOP PROGRAM

THURSDAY | 18 OCTOBER 2012

(MANCHESTER, BIRMINGHAM, AND GLASGOW-2 ROOMS)

08:00 REGISTRATION AND WELCOME COFFEE

08:45 **Welcome, introduction, and purpose of the workshop.** Jan Willem van der Laan,
Medicines Evaluation Board, The Netherlands

09:00 SESSION 1: SAFETY TESTING OF VACCINES AND ADJUVANTS
Session Chairperson: Sarah Gould, Sanofi, France

Overview. Sarah Gould, Sanofi, France.

Autoimmunity and immunisation? David Lewis, University of Surrey, UK.

09:45 COFFEE BREAK

10:15 SESSION 2: OIL-IN-WATER EMULSIONS
Session Chairperson: Deborah Novicki, Novartis, USA

Review of the literature on oils and oil-based adjuvants used in animal models of autoimmunity: Is there relevance to real-world adjuvant use? Deborah Novicki, Novartis, USA.

Structure-Activity Relationships of Oil-Based Adjuvant Formulations. Virgil Schijns, Wageningen University, The Netherlands.

Dissecting the Molecular Mechanisms of a Safe and Effective Adjuvant: The Oil in Water Emulsion, MF59. Nicholas Valiante, Novartis, USA.

Discussion

12:00 LUNCH (CITY CAFÉ)

13:30 SESSION 3: TLR-AGONISTS/ANTAGONISTS
Session Chairperson: Heather Davis, Pfizer, Canada

TLRs in Autoimmunity and Vaccines. Kingston Mills, Trinity College Dublin, Ireland.

AS04 Adjuvant System: from mechanism of action to safety evaluation. Marcelle Van Mechelen, GlaxoSmithKline, Belgium.

The role of the Toll-like receptors and autoimmune disease: An assessment of the state of the literature. David Clarke, Pfizer, USA.

Discussion

15:00 COFFEE BREAK

15:30 SESSION 4: ANIMAL MODELS AND BIOMARKERS FOR AUTOIMMUNITY
Session Chairperson: Lawrence Segal, GlaxoSmithKline, Belgium

Introduction to Use of Strains and Biomarkers for Evaluating the Risk of Autoimmunity. Lawrence Segal, GlaxoSmithKline, Belgium.

Autoantibodies, type I interferon and adjuvant-induced autoimmunity. Minoru Satoh, University of Florida, USA.

Therapeutic vaccination in chronic inflammatory diseases. Femke Broere, Utrecht University, The Netherlands.

MicroRNAs, a new paradigm to understand autoimmune pathogenesis and inflammation. S. Ansar Ahmed, Virginia Polytechnic Institute and State University, USA.

Discussion

17:00 REVIEW OF DAY ONE AND EXPLANATION OF WORKING DINNER QUESTIONS

17:30 ADJOURN UNTIL RECEPTION

19:00 NETWORKING RECEPTION (IN SKYLounge)

19:30 WORKING DINNER (BRISTOL 1 & 2 ROOMS)

During dinner the participants will discuss in small groups a series of questions, at least 1 or 2 per table, to be reported during the plenary session on Friday. The questions and the discussion will be used to reach consensus about recommendations for future evaluation.

FRIDAY | 19 OCTOBER 2012

(MANCHESTER, BIRMINGHAM, AND GLASGOW-2 ROOMS)

09:00 SESSION 5: NEW DEVELOPMENTS
Session Chairperson: Sarah Gould, Sanofi, France

'ASIA' - Autoimmune/inflammatory Syndrome Induced by Adjuvant. Nancy Agmon-Levin, Tel-Aviv University, Israel.

Pandemrix and risk of narcolepsy: immunological view. Outi Vaarala, National Institute for Health and Welfare, Finland.

10:30 COFFEE BREAK

11:00 SESSION 6: PLENARY REPORT AND DISCUSSION OF WORKING DINNER QUESTIONS, PART A
Session Chairperson: Jan Willem van der Laan, Medicines Evaluation Board, Netherlands

Discussion of the questions deliberated during the working dinner.

12:30 LUNCH (CITY CAFÉ)

14:00 SESSION 7: PLENARY REPORT OF WORKING DINNER QUESTIONS, PART B
Session Chairperson: Jan Willem van der Laan, Medicines Evaluation Board, Netherlands

Discussion of further questions introduced during the working dinner.

15:00 SUMMARY OF RECOMMENDATIONS

Discussion of writing and disseminating the workshop report. Development of key conclusions and potential impacts on existing study protocols and clinical trials.

15:30 END OF WORKSHOP