International Conference

"Development and Clinical Progress of DNA Vaccines"

Paul-Ehrlich-Institut, Langen, Germany

October 6-8, 1999

Program
INTERNATIONAL CONFERENCE

“Development and Clinical Progress of DNA Vaccines”

Paul-Ehrlich-Institut, Langen, Germany
October 6-8, 1999

You are cordially invited to an IABS International Conference on "Development and Clinical Progress of DNA Vaccines" hosted by the Paul-Ehrlich-Institut in Langen (near Frankfurt/Main), Germany, from 6th - 8th October, 1999. The conference is sponsored by IABS, NIBSC, WHO, NIAID/NIH, FDA/CBER and the Paul-Ehrlich-Institut.

This important international conference will review current developments and issues related to DNA vaccines which have the potential for becoming significant new biological products. Since the first demonstration of a protective effect conferred by a DNA vaccine in an animal model in 1993, this field has moved rapidly and recent human clinical trials have been highly encouraging. This conference will focus on new developments, animal models, regulatory aspects and results of recent clinical trials. The purpose of the conference is to:

1. identify major issues that need to be addressed in the development of DNA vaccines,
2. examine the ability of current technology to provide reliable data which support the safety and effectiveness of DNA vaccines,
3. develop a consensus on the types and amount of data needed to move forward in this area.
**Organizers:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tr>
<td>Klaus Cichutek</td>
<td>Dept. of Medical Biotechnology, Paul-Ehrlich-Institut, Langen, Germany</td>
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<td>James Robertson</td>
<td>NIBSC, Potters Bar, UK</td>
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**Program Committee:**

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<tr>
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<tr>
<td>Teresa Aguado</td>
<td>WHO, Vaccines and Other Biologicals, Geneva, Switzerland</td>
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<td>Klaus Cichutek</td>
<td>Dept. of Medical Biotechnology, Paul-Ehrlich-Institut, Langen, Germany</td>
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<td>William Egan</td>
<td>CBER/ FDA, Bethesda, U.S.A.</td>
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<td>Howard Engers</td>
<td>WHO, Disease Research and Development, Geneva, Switzerland</td>
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<tr>
<td>Uli Fruth</td>
<td>WHO, Vaccines and Other Biologicals, Geneva, Switzerland</td>
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<tr>
<td>Peter Liljeström</td>
<td>Karolinska Institute, Stockholm, Sweden</td>
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<tr>
<td>Margaret Liu</td>
<td>Chiron, Emeryville, U.S.A.</td>
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<td>Johannes Löwer</td>
<td>Paul-Ehrlich-Institut, Langen, Germany</td>
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<tr>
<td>Karin Mölling</td>
<td>Institute of Medical Virology, Zurich, Switzerland</td>
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<td>John Petricciani</td>
<td>IABS, U.S.A.</td>
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<td>Regina Rabinovich</td>
<td>NIAID, NIH, Bethesda, U.S.A.</td>
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<td>Martin Schleef</td>
<td>Qiagen, Duesseldorf, Germany</td>
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<td>David Weiner</td>
<td>University of Pennsylvania, Philadelphia, U.S.A.</td>
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**Wednesday, October 6, 1999**

**Registration**

Wednesday, October 6, 1999,  
10 a.m. – 4 p.m.  
Entrance Hall of the Paul-Ehrlich-Institut

Wednesday, October 6, 1999,  
after 4 p.m., until Friday, October 8  
Meeting Secretariat, Building 1, Floor 2 (2.OG), Paul-Ehrlich-Institut  
Office hours from Thursday to Friday: 8 a.m. until 1/2 hour after the end of the sessions.

**Conference Opening**

13:00 - 13:20 Welcome Addresses: Reinhard Kurth  
President of the Paul-Ehrlich-Institut

John Petricciani  
Vice-President of the IABS

Teresa Aguado  
WHO

William Egan  
CBER/FDA

Regina Rabinovich  
NIAID/NIH

James Robertson  
NIBSC

Klaus Cichutek  
Paul-Ehrlich-Institut
### Session 1: Basic Principles, Quality and Safety Assessment

**Moderators:**
- James Robertson, U. K.
- William Egan, U. S. A.

**13:20 - 13:45**
*An Inventors View of Some of the Uses and Limitations of Genetic Immunization*
Stephen A. Johnston, U. S. A.

**13:45 - 14:10**
*Mode of Action of DNA Vaccines*
Jeff Ulmer, U. S. A.

**14:10 - 14:30**
*Priming Polarized Immune Responses to Hepatitis B Virus Antigens by DNA Vaccination*
Jörg Reimann, Germany

**14:30 - 14:50**
*Progress in DNA Manufacturing and Quality Assurance*
Martin Schleef, Germany

**14:50 - 15:20**
**Coffee Break**

**15:20 - 15:40**
*Plasmid DNA Vaccines: Assay for Integration into the Host Genome*
Brian Ledwith, U. S. A.

**15:40 - 16:05**
*Safety Analysis of DNA Vaccines: Tolerance and Auto-Immunity*
Dennis Klinman, U. S. A.

**16:05 - 16:20**
*European Note for Guidance, Clinical Trial and Licensing Regulations Related to DNA Vaccines*
Klaus Cichutek, Germany / James Robertson, U. K.

**16:20 - 16:35**
*Regulation and Review of DNA Vaccine Products*
Herbert Smith, U. S. A.

**16:35 - 17:05**
Discussion
Speakers, Moderators, Audience

**17:05 - 17:30**
**Coffee Break**
Session 2: Presentation of Specific Topics (1)

Moderator: Uli Fruth, Switzerland

17:30 - 17:45  
**Induction of Immunity Using Oral DNA Vaccines Expressing the Measles Virus Nucleocapsid Protein**  
(*Selected for Oral Presentation from Submitted Abstracts*)  
Anthony R. Fooks, U. K.

17:45 - 18:10  
**Veterinary Applications of DNA Vaccines**  
Lorne Babiuk, CA

18:10 - 19:00  
**Break**

19:00 - 23:00  
**Poster Presentations**  
Buffet Dinner at Maxx Hotel
Session 3: DNA Vaccine Development in Larger Animals

Moderators: Johannes Löwer, Germany
Teresa Aguado, Switzerland

08:15 - 08:40  Augmentation of Immune Responses to HIV/SIV DNA Vaccines by IL-2/Ig Plasmid Administration in Rhesus Monkeys
Dan Barouch, U. S. A.

08:40 - 09:05  DNA Prime/Protein Boost Vaccine Strategy in Neonatal Macaques
Ruth Ruprecht, U. S. A.

09:05 - 09:30  Experimental DNA Vaccine Protection Against SIV/HIV Infection in Macaques
Marc Girard, France

09:30 - 09:55  DNA Priming and Recombinant Pox Virus Boosters for an AIDS Vaccine
Harriet Robinson, U. S. A.

09:55 - 10:25  Coffee Break

10:25 - 10:50  Lessons from DNA Vaccines for Measles in Macaques
Diane Griffin, U. S. A.

10:50 - 11:20  Discussion
Speakers, Moderators, Audience
Session 4: Clinical Experience

Moderators: Reinhard Kurth, Germany
Regina Rabinovich, U. S. A.

11:20 - 11:45 Immune Modulation in Cancer Using DNA Inoculation
Karin Mölling, Switzerland

11:45 - 12:10 Clinical Evaluation of a Powderject DNA Vaccine for Hepatitis B
William Swain, U. S. A.

12:10 - 12:35 Experience of Single and Multiple Genes in Human Immunization
Britta Wahren, Sweden

12:35 - 14:00 Lunch Break (Flugsicherung)

14:00 - 14:25 Can DNA Vaccines on Their Own be as Immunogenic and Protective as Prime-Boost Approaches to Immunization?
Stephen L. Hoffman, U. S. A.

14:25 - 14:50 From Benchtop to Clinic: Lessons Learned from Development of Facilitated DNA Vaccines
Richard Ginsberg, U. S. A.

14:50 - 15:15 Clinical DNA Vaccine Trials
N. N.

15:15 - 15:45 Discussion
Speakers, Moderators, Audience
Session 5: Presentation of Specific Topics (2)

Moderators: Reinhard Kurth, Germany
Regina Rabinovich, U. S. A.

15:45 - 16:00  Comparative Study of DNA Vaccines Encoding Various Antigens Against *Leishmania Mexicana*  
(Selected for Oral Presentation from Submitted Abstracts)*  
E. Dumonteil

16:00 - 17:15  Break

17:15  Departure from Maxx Hotel to Castle Auerbach

19:15  Dinner

22:30 – 23:30  Departure of Buses from Castle Auerbach to Maxx Hotel
Session 6: Improvement of DNA Vaccine Efficacy

Moderators: John Petricciani, U. S. A.
Uli Fruth, Switzerland

08:15 - 08:40 DNA-Based Immunization against Rabies and Rabies-Related Viruses: Towards Multivalent Vaccines
Noël Tordo, France

08:40 - 09:05 The Cellular Basis of Immune Induction at Mucosal Surfaces by DNA Vaccination
(Selected for Oral Presentation from Submitted Abstracts)*
Linda Klavinskis, U. K.

09:05 - 09:30 DNA Vaccines Based on Alphavirus Replicons
Peter Liljeström, Sweden

09:30 - 09:55 Humanized DNA Sequences for HIV Vaccine Development
John W. Shiver, U. S. A.

09:55 - 10:20 CpG Motifs and their Role in DNA Vaccines
Heather Davis, U. S. A.

10:20 - 10:50 Coffee Break

10:50 - 11:15 New Malaria Vaccines: The DNA-MVA Prime-Boost Approach
Adrian Hill, U. K.

11:15 - 11:40 DNA and Particle Alphavirus Replicons for Vaccine Applications
Tom Dubensky, U. S. A.

11:40 - 12:05 Multicomponent DNA Vaccines to Enhance Immune Responses
David B. Weiner, U. S. A.

12:05 - 12:35 Discussion
Speakers, Moderators, Audience

12:35 - 12:45 Concluding Remarks
Sponsors

12:45 - 13:00 Farewell
Johannes Löwer