



INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION

# International Alliance for Biological Standardization (IABS)



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## IABS BACKGROUND 'WHO WE ARE'

- A Scientific Society established in 1955
- Headquartered in Switzerland
- Recognized as a nonprofit organization in Switzerland and USA
- Officially recognized by *World Health Organization* (WHO) and *World Organisation for Animal Health* (OIE) as an organization that is in an official relationship with them



## IABS MISSION

To contribute to the scientific and medical advancement of Biologicals by **facilitating the communication** among those who develop, produce and regulate **biological products for human and animal health.**



## IABS OBJECTIVES

- To provide unique forum for consensus building among those who develop, produce and regulate biologicals.
- To promote use of international reference materials.
- To promote uniform methods for establishing the international quality of biological products.
- To promote the knowledge and use of international reference materials established by WHO and OIE.
- To encourage research on discovery, characterization, standardization, quality control, production, and clinical use of biological products.



## HOW IABS IS ORGANIZED

- **Membership:**

- Members are persons and institutions interested in biologicals

- **Structure**

- General Assembly – meets once every 2 years
- Board of Directors (15) – meets twice a year
- Executive Committee – meets about 10 times a year
- Affiliates in Europe & North America
- Committees: Human Vaccines, Veterinary Vaccines, Biotherapeutics, Cell & Gene Therapy, Communications



## IABS CORE ACTIVITIES

**Conferences:** More than 130 conferences and workshops have been organized.



Paul-Ehrlich-Institut

IABS, PEI and NEBIH  
are co-organizing an international workshop

Emerging Infectious Diseases of Animals:  
Strategies in Surveillance, Control and Eradication

28-30 September 2016 - Budapest, Hungary







## IABS CORE ACTIVITIES

**Proceedings of Conferences:** Published as Manuscripts or Meeting Reports (Conclusions and Recommendations) in *Biologicals* or otherwise available

**Where are we in our understanding of the association between narcolepsy and one of the 2009 adjuvanted influenza A (H1N1) vaccines?\***

K. Johansen <sup>a</sup>, D. Brasseur <sup>b</sup>, N. MacDonald <sup>c</sup>, H. Nohynek <sup>d</sup>, J. Vandeputte <sup>e</sup>, D. Wood <sup>f</sup>, P. Neels <sup>e, g, \*</sup>, on behalf of the Scientific Committee  
<sup>a</sup> Influenza and other Respiratory Viruses Disease Programme, Office of the Chief Scientist, Centre for Disease Prevention and Control, Stockholm, Sweden  
<sup>b</sup> Department of Paediatrics, Free University Brussels (ULB), Brussels, Belgium  
<sup>c</sup> Dalhousie University, IWK Health Center, Halifax, Nova Scotia, Canada  
<sup>d</sup> Vaccine Programme Development Team, Vaccine Programme Unit, National Institute for Public Health and Welfare, Helsinki, Finland  
<sup>e</sup> International Alliance on Biological Standards, Switzerland  
<sup>f</sup> Technologies Standards and Norms, Essential Medicines and Health Products, Geneva, Switzerland  
<sup>g</sup> Vaccine-Advice BVBA, University of Namur, Zoersel, Belgium

Evaluating new rare serious vaccine safety signals is difficult and complex. An observed increase in narcolepsy cases seen in Europe with the 2009 pandemic influenza A (H1N1) vaccine led the International Alliance for Biological Standardization (IABS) to invite a workshop meeting in Geneva in October 2015 to present data and to discuss the complex issue. The meeting covered the following topics: clinical picture of childhood narcolepsy; epidemiological and immunological studies conducted to assess the risk of narcolepsy following vaccination campaigns; potential genetic contribution to narcolepsy; epidemiological and immune-related diseases following 2009 pandemic H1N1 influenza vaccine; potential genetic biases influencing the different epidemiological study designs; potential genetic contribution to narcolepsy; potential biological mechanisms for development of narcolepsy in this setting; development of narcolepsy; potential biological mechanisms for development of narcolepsy in this setting; including the role of the virus itself, antigenic differences between the vaccines and differences in development of narcolepsy; potential biological mechanisms for development of narcolepsy in this setting; AS03-adjuvanted vaccines. The presentations were followed by fulsome roundtable discussions. Members from affected families also attended and made informal comments to round out the day's deliberations. This meeting emphasized the value added in bringing together in a neutral setting a wide range of experts and vaccine producers to discuss such a complex new serious adverse event following immunization.

**Report on the international workshop on alternative methods for Leptospira vaccine potency testing: State of the science and the way forward?\***

\*William Stokes<sup>a, 1</sup>, Geetha Srinivas<sup>b</sup>, Richard McFarland<sup>b</sup>, Jodie Kulpa-Eddy<sup>c</sup>, Warren Casey<sup>a</sup>, Angela Walker<sup>b</sup>, Hans Draayer<sup>c</sup>, Randy Sebring<sup>d</sup>, Karen Brown<sup>e</sup>, Elisabeth Balks<sup>b</sup>, Catrina Stirling<sup>d</sup>, Eric Klaassen<sup>d</sup>, Richard Hill<sup>b</sup>, Byron Rippke<sup>b</sup>, Kevin Ruby<sup>b</sup>, David Alt<sup>b</sup>, Suman Mukhopadhyay<sup>f</sup>, Hajime Kojima<sup>g</sup>, Nelson Johnson<sup>h</sup>, Lori Rinckel<sup>h</sup>, Vivian Doelling<sup>h</sup>, Brett Jones

Routine potency testing of *Leptospira* vaccines is mostly conducted using a vaccination-challenge test that involves large numbers of hamsters and unrelieved pain and distress. NICEATM, ICCVAM, and their international partners organized a workshop to review the state of the science of alternative methods that might replace, reduce, and refine the use of animals for veterinary *Leptospira* vaccine potency testing and to identify ways to advance improved alternative methods. Vaccine manufacturers were encouraged to initiate or continue product-specific validation using in vitro enzyme-linked immunosorbent assays as replacements for potency testing of four common *Leptospira* serogroups. Participants discussed the potential for eliminating the back-titration procedure in the hamster challenge assay, which could reduce the potential for animal use by 50% for each individual potency test. Further animal reduction may also be possible by using cryopreserved *Leptospira* stock to replace continual passaging through hamsters. Serology assays were identified as a way to further reduce and refine animal use but should be considered only after attempting in vitro assays. Workshop participants encouraged consideration of analgesics and use of earlier humane endpoints when the hamster vaccination-challenge potency assay is used. International harmonization of alternative potency methods was recommended to avoid duplicative potency testing to meet regionally different requirements.



## IABS CORE ACTIVITIES

### “*Biologicals*”

An international journal published by *Elsevier*, focused on biological product development and issues







## THE SCIENTIFIC CONFERENCES

- The Scientific Committees (Human Vaccines, Human Biotherapeutics, Human Cell & Gene Therapy, Veterinary Biologicals) are responsible for the organization of the conferences along with Collaborators and Partners
- The topics correspond to current issues of interest for the Industry & Regulatory Agencies; addressing current regulatory science
- The speakers & session chairs are recognized experts
- Designated rapporteurs assure publication of a conference summary in *Biologicals* or elsewhere
- The final conference session is dedicated to the preparation of “*Conclusions & Recommendations*” which are promptly published with selected papers available electronically



## EXAMPLE OF THE IMPACT OF AN IABS CONFERENCE

- **2004 Conference on cell substrates for vaccine production – especially Continuous Cell Lines:**
  - ✓ Recommendation: WHO should revise its guidance document on cell substrates
  - ✓ WHO established a Study Group in 2006
  - ✓ Draft revisions developed and made available for public comment
  - ✓ Final draft adopted by WHO Expert Committee on Biological Standardization in 2010
  - ✓ WHO implementation workshop in Beijing in 2013



## EXAMPLE OF THE IMPACT OF AN IABS CONFERENCE

- **2011 Conference on adventitious agents and risk assessment (follow-up to finding PCV in rotavirus vaccines):**
  - ✓ Consideration of WHO draft risk assessment document
  - ✓ Public comments
  - ✓ Development of Case Studies (past examples)
  - ✓ 2013 WHO workshop
  - ✓ Publication of principles of risk assessment & case studies in *Biologicals* (early 2014)
  - ✓ WHO Expert Committee on Biological Standardization adopted Regulatory Risk Evaluation Guidance for Contaminated Vaccines (2014)



## CONTRIBUTIONS TO SUCCESS

- WHO study group: guidance for industry and NRAs on cell substrates for production of vaccines and biotherapeutics
- Neurovirulence tests for live vaccines; Vaccine Stability evaluation
- Progressing Animal Welfare and Reduce, Refine, and Replace (3R) Initiatives
- FDA guidance on Immunogenicity, related to particulates in therapeutic Protein products
- Adequate studies and regulatory progress on Unwanted Immunogenicity
- Adventitious agents, New technology and Risk Assessment
- Viral Safety and Extraneous Agents testing for Veterinary Vaccines



## TRANSPARENCY AND NEUTRALITY

- With the growing concern of the potential for Conflict of Interest, the IABS established a process to maximise transparency and neutrality
- Because this neutrality is now recognized, IABS is a unique organization which gathers leaders of for-profit and non-profit organizations in a search for solutions to issues in both human and animal health related to biological products



## IABS REGIONAL AFFILIATES


- European and North American Affiliates of IABS (IABS-EU; IABS-NA; IABS-Asia in process)
- Enhance IABS activities and further develop its outreach within the region
- Focus on issues concerning the regulation and standardization of biological products that are intended for commercial use in the region
- Particular attention to the regional impact of innovation on regulatory issues for biologicals in human and animal health
- Other Regions under discussion






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# UPCOMING SCIENTIFIC CONFERENCES

 INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION

**Autogenous Vaccines  
and Their Role in Animal Health Strategy**

September 25-26, 2017 - Het Pand, University of Ghent, Belgium




 INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION

**4<sup>th</sup> International Workshop on Statistical and Data Management  
Approaches for Biotechnology Drug Development**

October 30 - November 1, 2017 - Rockville, Maryland






 INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION

**2<sup>nd</sup> Human Challenge Trials**

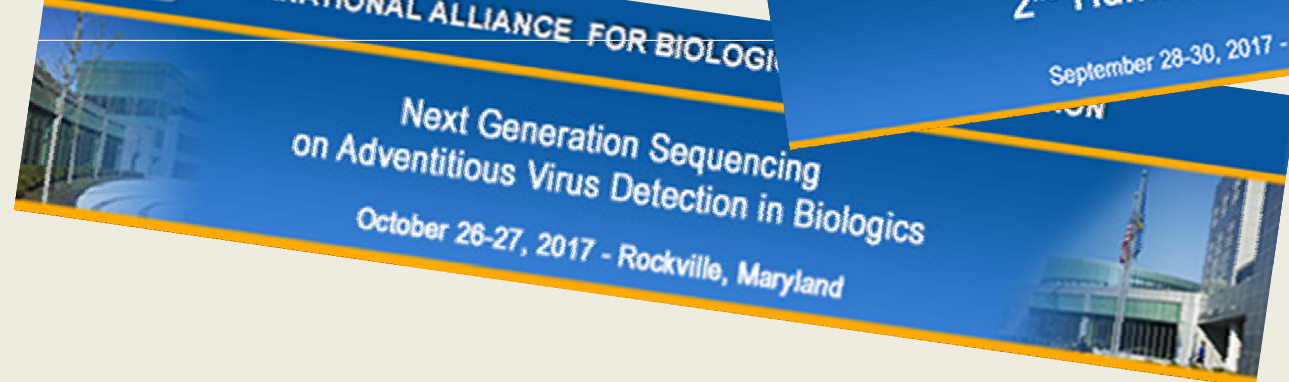
September 28-30, 2017 - Rockville, Maryland



 INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION

**Next Generation Sequencing  
on Adventitious Virus Detection in Biologics**

October 26-27, 2017 - Rockville, Maryland







## UPCOMING SCIENTIFIC CONFERENCES

- **Autogenous Vaccines and Their Role in Animal Health Strategy**  
September 25-26, 2017 - Co-organized with University of Ghent, Belgium
- **2nd Human Challenge Trials Workshop**  
September 28-30, 2017, Rockville, Maryland, USA
- **Next Generation Sequencing**  
October 26-27, 2017, Rockville, Maryland, USA
- **4<sup>th</sup> Statistical and Data Management Approaches for Biotechnology Drug Development**  
October 30 - November 1, 2017, Rockville, Maryland, USA  
Co-organized IABS – FDA
- **Latest technologies for the characterization and control of biotechnology products**  
November 6-8, 2017, Gaithersburg, Maryland, USA  
Co-organized with NIST



## INFORMATION AND CONTACTS

- **Dr. Joris Vandeputte:** President: *joris.vandeputte @iabs.org*
- **Dr. John Petricciani,** Immediate Past-President: *PetriccianilABS@aol.com*
- **Dr. Daniel Gaudry,** Secretary : *daniel.gaudry@iabs.org*
- **Ms. Abbie Charlet,** Head of the Scientific Secretariat: *abbie.charlet@iabs.org*
- The Scientific Committee chairs:
  - **Dr. Pieter Neels,** Chair of the Human Vaccine Committee
  - **Dr. Carmen Jungbäck,** Chair of the Veterinary Vaccine Committee
  - **Dr. Tony Mire-Sluis,** Chair of the Human Biotherapeutics Committee
  - **Dr. Takao Hayakawa,** Chair of the Human Cell and Gene Committee

Additional information may be found at: **[www.iabs.org](http://www.iabs.org)**