



**Implementing non-animal approaches to human and veterinary vaccine testing:  
Achieving scientific and regulatory success for rabies and beyond**

National Institutes of Health  
Natcher Conference Center  
Bethesda, Maryland  
16-17 October 2018

**Day 1 – October 16, 2018**

7:30 **Registration** Poster Set Up

**Session 1**

**Welcome from the Organizers**

**Moderator:** Robin Levis, Food and Drug Administration (FDA)

8:00 **Warren Casey**, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

8:15 **Richard Hill**, International Alliance for Biological Standardization – North America (IABS)

**Session 2**

**Setting the Stage for Alternatives to *In Vivo* Release Testing for Animal and Human Vaccines**

**Moderator:** Richard Hill, IABS

8:30 Human Biologics - North American Regulatory Perspective  
**Robin Levis**, FDA

9:00 Animal Biologics - North American Regulatory Perspective  
**Geetha Srinivas**, U.S. Department of Agriculture (USDA) – Center for Veterinary Biologics (CVB)

9:30 The “Consistency Approach”: Concept and Progress Since the 2015 Congress  
**Marlies Halder**, European Commission Joint Research Center (JRC)

9:50 Rabies and the Innovative Medicines Initiative, Vaccine Lot to Vaccine Lot Comparison by Consistency Testing (IMI Vac2Vac)  
**Catrina Stirling**, Zoetis

10:10 **Break** Poster session available for viewing

10:30 Substitutions for In Vivo Methods and Potency Test Acceptability: The Fear Factor  
**Dean Smith**, Health Canada

10:50 A Success Story of Alternatives to In Vivo Testing: Pertussis Vaccine Histamine Sensitization Test (HIST) Waiving and Replacement  
**Juan Arciniega**, FDA (retired)

11:10 Drivers and Barriers to Replacing the NIH Test for Rabies Vaccine Potency Testing  
**Marie-Jeanne Schiffelers**, Utrecht University



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### Session 3

#### Rabies Vaccines Alternative Testing - State of the Art and Reagent Availability

**Moderator:** Robin Levis, Food & Drug Administration – FDA

- 11:30 Reagents and Serology  
**Marc Fiorucci**, Boehringer Ingelheim Animal Health
- 11:50 Animal Health Institute (AHI) Veterinary Biologics Section (VBS) Rabies Potency Test Working Group -  
Technical and Procedural Perspectives  
**Nancy Oien**, Zoetis
- 12:10 **Break** Poster session available for viewing
- 13:10 Overview of European Partnership for Alternatives to Animal Testing (EPAA) Efforts on Replacement of  
Animal Testing for Rabies Vaccine and Reagent Availability  
**JM Chapsal**, EPAA
- 13:30 Overview of European Directorate for the Quality of Medicines and Healthcare (EDQM) - Efforts in the  
Rabies Space  
**Eriko Terao**, European Partnership for Alternative Approaches to Animal Testing (EPAA)
- 13:50 An ELISA for Human Rabies Vaccine - Method Validation Leading to Selection for EDQM  
**Patrice Riou**, Sanofi Pasteur.
- 14:10 Use of ELISA for a New Human Rabies Vaccine: Clinical Trial for a Dose Ranging Study  
**Francoise Guinet-Morlot**, Sanofi Pasteur
- 14:20 An ELISA for Veterinary Vaccine: Validation and Acceptance by EMA as an Alternative to NIH Rabies Test  
**Marc Fiorucci**, Boehringer Ingelheim Animal Health
- 14:40 Development of In Vitro and In Vivo Rabies Virus Neutralization Assays Based on a High Titer Pseudovirus  
System  
**Xuguang Li**, Health Canada – Centre for Biologics Evaluation, Biologics and Genetic Therapies  
Directorate
- 15:00 **Break** Poster session available for viewing

### Session 4

#### Charting the Path Forward for Alternative Testing for Rabies Vaccines

**Moderator:** Laurent Mallet

- 15:10 Roundtable 1 – Setting the Stage  
**Moderators:**  
Veterinary Rabies Focus –**Catrina Stirling**, Zoetis  
Human Rabies Focus - **Cynthia Allen**, Health Canada  
Setting Aspirational Outcomes for the Workshop and Roundtables.

#### Poster Session – Alternatives to Vaccine Testing in Animals - Beyond Rabies

16:30 – 18:00



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**Day 2 – October 17, 2018**

**Session 4, continued**

**Charting the Path Forward for Alternative Testing for Rabies**

(Veterinary and human focus groups will meet separately for majority of Roundtables)

**Moderator:** Laurent Mallet

- 8:30 Keynote address:  
Alternatives to Animal Testing – Rabies and Beyond  
**Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group
- 9:00 Brief review of Day 1 Progress and Refinements on Roundtable Goals for Day 2  
Veterinary Rabies Focus –**Catrina Stirling**, Zoetis  
Human Rabies Focus - **Cynthia Allen**, Health Canada
- 9:15 **Roundtable 2** – Ideation and Action  
**Moderators:**  
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group  
Human Rabies Focus – **Dean Smith**, Health Canada
- 12:00 **Break** - poster session breakdown
- 13:20 Joint Session - Regulatory and industry speakers will highlight key items.  
Items may include specific challenges, methods to expedite research and regulatory changes
- 13:20 Regulatory Considerations from the Veterinary and Human Perspective  
Veterinary Regulatory – **Speaker**  
Human Regulatory – **Speaker**
- 13:40 Industry Considerations from the Veterinary and Human Perspective  
Veterinary Industry – **Speaker**  
Human Industry – **Speaker**
- 14:00 **Roundtable 3** – Drafting the Roadmap  
**Co-moderators** from Roundtables 1&2:  
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group and **Catrina Stirling**, Zoetis  
Human Rabies Focus – **Dean Smith**, Health Canada; **Cynthia Allen**, Health Canada
- 15:30 Break

**Session 5**

**Rabies Alternative Testing Wrap-up**

**Global Perspective and Future Considerations**

**Moderator:** Warren Casey

- 15:45 Veterinary and Human Roadmaps  
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group; and **Catrina**



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**Stirling**, Zoetis

Human Rabies Focus – **Dean Smith**; **Cynthia Allen**, Health Canada

16:20 Global Perspective and Future Considerations for Decreasing Testing in Animals  
**Rebecca Sheets**, IABS

16:40 Closing Conference Comments  
**Warren Casey**, NICEATM  
**Richard Hill**, IABS  
**Robin Levis**, FDA

**Scientific Program Committee**

**CO-CHAIRS**

Warren Casey, NICEATM

Robin Levis, FDA

Richard Hill, IABS

**MEMBERS**

Juan Arciniega, FDA (ret)

Geetha Srinivas, USDA – Center for Veterinary Biologics

Yvette Diamondidis, Zoetis

Cynthia Allen, Health Canada - Center for Biologics Evaluation

Oksana Yarosh, Health Canada - Canadian Food Inspection Agency's Canadian Centre for Veterinary Biologics

Laurent Mallet, Sanofi

Rodney Christmas, Boehringer Ingelheim Animal Health

James Roth, Institute for International - Cooperation in Animal Biologics/ Center for Food Security and Public Health

Laura Viviani, Humane Society International

Gautam Sanyal, Bill & Melinda Gates Foundation

Jeffrey Brown, People for Ethical Treatment of Animals-International Science Consortium

**Organizing Committee**

Dave Allen, Integrated Laboratory Systems, Inc. (ILS)

Rebecca Poston, ILS (Consultant)

Steven Morefield, ILS

Rebecca Sheets, IABS

Abbie Charlet, IABS