

# Current Efforts in African Swine Fever Vaccines: *A Virtual Seminar and Discussion*

Thursday, May 6, 2021  
9:00 AM - 12:30 PM EDT

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STAR-IDAZ  
International Research  
Consortium on Animal Health

9:00 AM EDT | Log-on and Technology Check

**Ms. Hayley Harman**, CRDF Global

9:05 AM EDT | Opening remarks

**Dr. Cyril Gay**, Global African Swine Fever Research Alliance (GARA), *United States of America*

**Dr. Miia Jakava-Viljanen**, International Alliance for Biological Standardization (IABS), *Finland*

9:15 AM EDT | Keynote: ASF vaccines and current developments at USDA

**Dr. Douglas Gladue**, U.S. Department of Agriculture, *United States of America*

10:00 AM EDT | Session 1: Recent Advances on ASFV Vaccines at Harbin, including ASFV-SY18-ΔCD2v/UK

**Dr. Hua-Ji Qiu**, Harbin Veterinary Research Institute, *China*

10:20 AM EDT | Session 2: Recent Advances on ASFV Vaccines at VacDiva

**Dr. Jose Manuel Sanchez-Vizcaino Rodriguez**, VISAVET Health Surveillance Centre, *Spain*

10:40 AM EDT | Session 3: Recent Advances in ASFV Vaccines at ILRI

**Dr. Lucilla Steinaa**, International Livestock Research Institute (ILRI), *Kenya*

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10:55 AM EDT | Break

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11:05 AM EDT | Session 4: Key Regulatory Challenges for Licensing ASF Vaccines

European Medicines Agency Support to bring Vaccines to Market in the EU

**Dr. Ivo Claassen**, European Medicines Agency, *The Netherlands*

Live Attenuated Vaccines Safety Studies

**Dr. David Mackay**, Independent Advisor, *United Kingdom*

11:25 AM EDT | Roundtable Discussion

Chaired by **Dr. Joris Vandeputte**, President IABS

**Dr. Douglas Gladue**, U.S. Department of Agriculture, *United States of America*

**Dr. Hua-Ji Qiu**, Harbin Veterinary Research Institute, *China*

**Dr. Jose Manuel Sanchez-Vizcaino Rodriguez**, VISAVET Health Surveillance Centre, *Spain*

**Dr. Alicia Urniza**, Zoetis, *Spain*

**Dr. Egbert Mundt**, Boehringer Ingelheim Animal Health, *Germany*

12:20 PM EDT | Closing Remarks

**Dr. Alex Morrow**, International Research Consortium on Animal Health (STAR-IDAZ), *United Kingdom*

12:30 PM EDT | Adjourn

Our Speakers:

**Dr. Cyril Gay**, Global African Swine Fever Research Alliance (GARA), *United States of America*



Dr. Gay is a recognized subject matter expert on agricultural research, biodefense, vaccines, and strategic technology transfers. Dr. Gay obtained a Doctor of Veterinary Medicine degree from Auburn University, and a Ph.D. in Microbiology from The George Washington University. Dr. Gay has worked in the animal health research field for the last 30 years holding several positions of increasing responsibility in the pharmaceutical industry and the U.S government. As Chief of Biotechnology, Center for Veterinary Biologics, USDA, Dr. Gay developed the procedures for licensing molecular vaccines that led to the first license for a live recombinant vectored vaccine. In the pharmaceutical industry. Dr. Gay led several cross-functional teams in the pharmaceutical industry that successfully developed and licensed veterinary vaccines.

Dr. Gay joined Agricultural Research Service (ARS), USDA, in 2002. At ARS, Dr. Gay developed a national research program responsive to problems of high national priority with demonstrated impact on animal health and public health worldwide. Dr. Gay currently holds the position of Senior National Program Leader and provides program direction and national coordination for the Department's intramural animal health research program, including the National Animal Disease Center, Ames, Iowa; National Poultry Research Center, Athens, Georgia; Plum Island Animal Disease Center, Orient Point, New York; Animal Diseases Research Laboratory, Pullman, Washington; Arthropod-Borne Animal Diseases Laboratory, Manhattan, Kansas. Dr. Gay was recipient of two Pfizer Animal Health Presidential awards, the USDA Secretary's Honors Award for interagency response to the pandemic H1N1 influenza outbreak, the ARS Special Administrator's Award for outstanding and rapid research support for pandemic H1N1, and a meritorious U.S Presidential Rank Award in 2017.

**Dr. Miia Jakava-Viljanen**, International Alliance for Biological Standardization (IABS), *Finland*



Following positions at the Helsinki University in Finland in teaching microbiology, immunology and epidemiology, and research, as a veterinarian, Dr Miia Jakava-Viljanen joined the Finnish Food Authority as Head of Section involved in virology, epidemiology and veterinary vaccines, and batch release and testing of vaccines. She subsequently moved into the policy area, assuming the post of Government Counsellor at the Ministry of Agriculture and Forestry of Finland worked with Animal Health and Welfare legislation, rabies, pet movement, bee health, animals used for scientific purposes (3Rs), EU co-financed programs, funding for research projects and collaboration with Russia. Seconded to the European Commission, she was involved in the implementation of the EU legislation on Animal Health and participated to the work on EU climate change. She joined the European Medicines Agency in 2014 - 2019 as National Expert where she was responsible to provide consultation and expertise specifically in the area of veterinary biologicals, immunological medicines and emerging therapies, EU legislation and policy as scientific/content lead. Currently she is working at the Finnish Food Authority.

She is an expert of EDQM European Pharmacopoeia Group 15V (vaccines and sera) since 2002. She joined IABS in 2019 and is a member of the executive board and the Chair of the Veterinary Biologicals Committee. She is organizing IABS meetings focusing on the veterinary field.

**Dr. Douglas Gladue**, U.S. Department of Agriculture, *United States of America*



Douglas Gladue, PhD is a Senior Scientist at the USDA Plum Island Animal Disease Center focusing on rationally designed vaccines for foreign swine diseases including African swine fever virus (ASFV). Dr. Gladue started his research on swine diseases in 2007 focusing on developing a novel rationally designed ASFV vaccine. Currently he is co-inventor on five effective live attenuated vaccine platforms against ASFV. His recent accomplishments include identification of a stable cell line for ASFV diagnostics and ASFV vaccine production, the functional characterization of ASFV proteins, and the development of new methodology for independent multiple deletions in the ASFV genome, allowing for safer ASFV vaccine design strategies. Dr. Gladue was elected as the Scientific Director for the global alliance for ASFV (GARA). Other than ASFV, his research interests also include classical swine fever virus (CSFV) and foot-and-mouth disease virus (FMDV), where he has focused on the molecular mechanisms of viral pathogenesis and virus-host protein interactions and applying these discoveries to the design of rational vaccines. He has discovered over one hundred host-viral protein interactions and has used this discovery combined with a custom computational pipeline involving both bioinformatics and functional genomic data to identify critical domains in viral proteins. Dr. Gladue has served on multiple scientific committees, grant review panels, and authored numerous peer-reviewed scientific publications. He currently serves as an editor for several scientific journals, and as treasurer-elect for the world society of virology.

**Dr. Hua-Ji Qiu**, Harbin Veterinary Research Institute, *China*



Dr. Hua-Ji Qiu, PhD, DVM, professor, the chief scientist of the Unit for High-Consequence Swine Viral Diseases, Harbin Veterinary Research Institute, CAAS, China. He served as coordinator of more than 20 projects from National “863” Program, National Natural Science Foundation of China, National Key Technologies R&D Program, EU FP7 project, etc. His research is focused on the regulation of viral replication, virulence determinants and development of diagnostic assays and marker vaccines for classical swine fever, African swine fever and pseudorabies. He has been awarded several national and provincial prizes for progress in science and technology. He has published more than 70 papers in SCI-indexed journals, including 11 papers in *Journal of Virology*.

Dr. Qiu is a member of the Asfarviridae Study Group of ICTV, a member of National Committee of Experts on Animal Epidemic Prevention of China, and a standing member of Animal Infectious Diseases Branch and a member of Veterinary Biotechnology Branch of Chinese Society of Animal Husbandry and Veterinary. He is an editor of several journals such as *Frontiers in Immunology*, *Scientia Agricultura Sinica*, *Chinese Journal of Biotechnology*, *Acta Microbiologia Sinica*, etc., and a peer reviewer of a number of international journals such as *Gene Therapy*, *Journal of Virology*, *Vaccine*, *Veterinary Microbiology*, *Viruses*, *Virus Research*, etc.

**Dr. Jose Manuel Sanchez-Vizcaino Rodriguez**, VISAVET Health Surveillance Centre, *Spain*



Dr. José Sánchez-Vizcaíno obtained his DVM and Ph.D from the Complutense University of Madrid, completing his postgraduate studies in immunology and animal virology at Cornell University, New York. Upon his return to Spain, he joined the National Institute of Agricultural and Food Research (INIA) where he developed his scientific and research work as Head of the Department of Animal Virology (1985-1988), Head of the Department of Animal Health (1988-1993) and Founder Director of the BSL3+ at the Animal Health Research Center (CISA-INIA) (1993-2002). Since 2002, he is Full Professor of Animal Health

at the Complutense University of Madrid (UCM) and Director of the Reference Laboratory of the World Organization for Animal Health (OIE) for African swine fever (ASF).

He has more than 240 scientific publications in high impact international journals. He is the author of 47 chapters in internationally renowned books. He has been the IP of more than 150 national and international competitive research projects and director of 34 doctoral theses. He has been awarded the Commendation of Number of the Order of Agrarian Merit (12/03/99) and of Food Merit (05/05/03), the Cross of Military Merit with white distinctive (03/01/03), all this is due to his contributions in animal health and in the control of infectious diseases, as well as internationally, with the Medal of Merit from the World Organization for Animal Health (OIE) as international recognition for his outstanding services to world veterinary science (Paris , 5/24/2009). Likewise, as Doctor Honoris Causa by the University of Murcia (04/22/2010) and nominated "2013 George C. Poppensiek Visiting Professor in Global Animal Health" by Cornell University (09/2013), among other academic and scientific distinctions .

His current scientific interest is focused on the study of the epidemiology and preventive medicine of infectious diseases of animals, as well as the development of new diagnostic techniques, new generation vaccines and new strategies for their control. He is currently the coordinator of the EU VACDIVA project for "a safe and effective vaccine against ASF DIVA. More information: <https://www.sanidadanimal.info/es/>

**Dr. Lucilla Steinaa**, International Livestock Research Institute (ILRI), *Kenya*



Dr. Lucilla Steinaa, Principal Scientist at ILRI, obtained her MSc degree in 1992. After this she worked as Scientist at a danish hospital and later in a Biotech Company. She obtained her PhD at University of Copenhagen jointly with a Biotech company in Denmark in 2002 in the immunological field. She stayed in the Biotech sector where she was involved in developing proprietary technology platforms and products in the vaccine area and in the therapeutic antibody area. She was involved in various subject areas such as cancer, autoimmune diseases and infectious diseases working with pathogens, such as HIV, RSV and Vaccinia. In 2009, she relocated to Kenya and started as Senior Scientist at ILRI, working on the development of a vaccine for the cattle disease East Coast fever (ECF). Later, she initiated vaccine research for control of African swine fever, where she now leads projects for developing an attenuated vaccine using gene editing and a subunit vaccine for control of African swine fever. She has recently received funding to use the established gene editing technologies for attenuation of the parasite *Theileria parva*, the causative agent of ECF, in order to improve on the live vaccination strategy, and she also does some molecular epidemiology research on bluetongue virus. She has about 30 years of experience in conducting and managing research projects from both the human and veterinary health area.

**Dr. Ivo Claassen**, European Medicines Agency, *The Netherlands*



In 2018, Ivo Claassen joined the European Medicines Agency (EMA) as Head of the Veterinary Medicines Division. He is the co-chair of the joint EMA-HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation. He is the accountable executive for the development and implementation of the IT-systems supporting the Veterinary Regulation. He is a former member of EMA's Committee for Medicinal Products for Veterinary Use (CVMP).

Dr Claassen has over 30 years of experience in vaccine production, quality assurance and control, research and development and regulatory affairs, both for human and veterinary vaccines. Before joining the Agency, he

developed projects in Asia, Africa and the Middle East on capacity building of institutional infrastructure for veterinary infectious disease control and supported local vaccine development and production.

**Dr. David Mackay**, Independent Advisor, *United Kingdom*



David qualified as a veterinary surgeon and worked in general veterinary practice before obtaining postgraduate degrees in immunology from the Universities of Birmingham and London. He then embarked on a research career in exotic viral diseases of livestock culminating as Head of the Pirbright Laboratory of the Institute for Animal Health. David subsequently moved into the regulatory area, assuming leadership of the Immunologicals Team at the Veterinary Medicines Directorate in the UK before becoming the Director of Licensing. David then moved to the European Medicines Agency in charge of the Veterinary Medicines Division. During his career he has published on epizootic diseases of livestock and on regulatory issues, particularly in relation to veterinary vaccines. David retired from the EMA in 2018 and now provides independent advice to governmental and not-for-profit organisations in relation to regulation and use of veterinary medicines.

**Dr. Joris Vandeputte**, President IABS



Dr. Joris Vandeputte is President of IABS (International Alliance for Biological Standardization) and a founding member of IABS-EU, the European affiliate of IABS. Since 1955, IABS has been the global independent platform for stakeholders to discuss the science and issues related to vaccines, cell and gene therapy, and human Biotherapeutics. IABS stimulates consensus building that eventually results in regulatory frameworks and recommendations to decision makers. In the current COVID-19 pandemic, IABS is organizing many stakeholder exchanges via webinar and publications to strengthen development access to vaccines and treatment for COVID-19.

**Dr. Alicia Urniza**, Zoetis, *Spain*



Alicia supervises European R&D discovery and development activities for vaccines for both livestock and companion animals at Zoetis. She is also VMRD Site Lead in the Zoetis facilities in Spain (Olot) and is part of the Global Zoetis Animal Welfare Board. Alicia received her DVM from University of Barcelona, Spain. She has more than 20 years' experience in Research and Development for animal vaccines. She and her team have contributed to the development and approval of many biologicals and have brought numerous first in class Emerging Infectious Diseases vaccines; among the latest approvals were Suvaxyn® CSF Marker (Classical Swine Fever virus), Suvaxyn® PRRS MLV, Zulvac® SBV (Schmallenberg virus), Zulvac® BTV Ovis (Multistrain dossier for Bluetongue), Versican Plus Bb Oral (oral vaccine against *Bordetella Bronchiseptica* for dogs).

**Dr. Egbert Mundt**, Boehringer Ingelheim Animal Health, *Germany*



Dr. Egbert Mundt graduated as DVM from the Veterinary College of the Humboldt University Berlin, in 1989. He started his work in poultry virology at the Friedrich Loeffler Institute, Insel Riems, Germany at the same year.

From 1992 to 2006, Dr. Mundt served as staff scientist and later group leader at the Federal Research Institute for Animal Health, Insel Riems, Germany. He obtained his PhD in molecular virology at the Veterinary College of the University Giessen in 1995 and has served as both a visiting scientist at the Veterinary College of the University of Maryland in 1995 the Endowed Chair as Caswell Eidson Chair in Poultry Medicine at the University of Georgia in Athens.

In 2011 Dr. Mundt started his career in the pharmaceutical industry as Department Head Viral Vaccines at the IDT GmbH, Dessau, Germany. In 2012, he took his first position at Boehringer Ingelheim Vetmedica GmbH as Head Global Poultry Vaccine R&D, and eventually served for three years as the Global Head of Vaccine Design R&D. Since January 2021, Dr. Mundt heads a division named New Biological Entities at Boehringer Ingelheim Animal Health Global Innovation in Lyon, France. Dr. Mundt's research focuses on molecular virology of diseases of food producing animals and associated technologies for vaccine development including basic research.

He has published more than 70 peer-reviewed publications, chapters in several books and holds several patents. In addition, he is member of the Taxonomy Committee for Birna and Picobirnaviridae and participates in several scientific committees.

**Dr. Alex Morrow**, International Research Consortium on Animal Health (STAR-IDAZ), *United Kingdom*



Dr. Alex Morrow, BA, MVB, PhD, MRCVS is veterinary surgeon with seventeen years' experience in research working on the pathogenesis and control of *Amblyomma variegatum*-associated dermatophilosis, followed by four years in a research support capacity at Edinburgh University and seventeen years in research programme management with Defra where he was International Evidence Lead for Animal Health and Welfare. He is currently a CABI Associate.

He established and coordinated for 10 years the European Collaborative Working Group (CWG) on Animal Health and Welfare Research, under the EU Standing Committee on Agriculture Research, and led the associated EU-funded EMIDA ERA-NET on Emerging and Major Infectious Diseases of Animals. This ERA-NET ran two common calls funding 26 transnational research projects with a combined budget of over €40million. He led the STAR-IDAZ global network, "Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses" during the first six years of its existence, and oversaw the formation of the associated International Research Consortium (IRC), with a higher level of commitment to collaboration, which was launched by the European Commission in January 2016. He now also heads the EU-funded IRC secretariat.