OIE Collaborating Centres Reports Activities

Activities in 2021

This report has been submitted : 2022-01-19 04:36:50

Title of collaborating centre:	Veterinary Drug Regulatory Programmes
Address of Collaborating Centre:	Food and Drug Administration (FDA) Department of Health and Human Services 7500 Standish Place, HFV-1, Room 177 Rockville, Maryland 20855 UNITED STATES OF AMERICA
Tel.:	+1-202-631-0104
Fax:	
E-mail address:	Ellen.Hart@fda.hhs.gov
Website:	www.fda.gov/AnimalVeterinary/default.htm
Name of Director of Institute (Responsible Official):	Dr. Steven M. Solomon
Name (including Title and Position) of Head of the Collaborating Centre (formally OIE Contact Point):	Dr. Ellen J Hart, Acting Director, International Programs and Outreach
Name of writer:	Dr. Ellen J Hart

ToR: To provide services to the OIE, in particular within the region, in the designated specialty, in support of the implementation of OIE policies and, where required, seek for collaboration with OIE Reference Laboratories

ToR: To identify and maintain existing expertise, in particular within its region

1. Activities as a centre of research, expertise, standardisation and dissemination of techniques within the remit of the mandate given by the OIE

Training, capacity building	
Title of activity	**Scope**
Participated in Regional Training Seminar for OIE National Focal Points for Veterinary Products (Americas, Cycle VI), Virtual April 20-21, 2021	The sixth cycle training course focused on antimicrobial resistance and prudent use of antimicrobials, antiparasitic resistance, global access to quality products, international harmonization standards for veterinary medicinal products (VICH), pharmacovigilance, and substandard and falsified (counterfeit) products. CVM experts led hands-on working group sessions on requirements for pharmacovigilance systems and surveillance, and antiparasitic resistance, reviewing the results of regionally distributed surveys.
Committee for Veterinary Medicines of the Americas (CAMEVET), Virtual November 17-19th, 2021	The American Committee for Veterinary Medicines (CAMEVET) is a regional project which aims to facilitate the harmonization of standards, records, and control of veterinary medicines among member countries. CVM presented on “The Importance of the Human Intestinal Microbiome in FDA’s Pre-Approval Evaluation of Drugs for Food Producing Animals.”
Question and Answer Session in follow up to the 13th VICH Outreach Forum, Virtual, February 9, 2021	FDA recorded a presentation on the implementation of VICH GL 27 on antimicrobial resistance, which was shared with participants in the 13th VICH Outreach Forum November 16, 2021. Presenters participated in a follow up webinar the following February to address questions from VICH Outreach Forum Members on the content of the recorded presentation.
Participated in the 14th VICH Outreach Forum, Virtual, November 16, 2021	The 14th Session of the VICH Outreach Forum was held virtually. To make the best use of participants’ time, presentations were recorded and made available to participants and their organizations. CVM provided a recorded presentation on how VICH GLs on environmental risk assessment are implemented in the United States.
Aquatic animal diseases	
Title of activity	**Scope**
FAO’s Fish-Vet Dialogue: Exploring Collaboration on Managing Health of Aquatic Organisms, June 6-9, 2021	Participated in a forum to exchange information on experiences and potential areas for collaboration concerning aquaculture biosecurity and health management of aquatic organisms.
Diagnosis, biotechnology and laboratory	
Title of activity	**Scope**

CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Interlaboratory Comparison Exercises	In coordination with other US federal agencies, including other OIE collaborating centers (CDC and USDA), carried out interlaboratory comparison exercises for laboratories testing animal samples for SARS-CoV-2.
One Health Federal Interagency COVID-19 Coordination (OH-FICC) group	In coordination with other US federal agencies, including other OIE collaborating centers (CDC and USDA), coordinated the United States' One Health response to the COVID-19 pandemic, including animal diagnostics and testing and furthering efforts to standardize procedures, prioritize testing, and report animal test results.
National Antimicrobial Resistance Monitoring System (NARMS)	In coordination with USDA, EPA and other collaborators, determined resistance to antimicrobial drugs in animals, humans, and food. Initiated studies to test rivers and streams for AMR genes and bacteria.
Veterinary medicinal products	
Title of activity	**Scope**
40th VICH Steering Committee and 14th Outreach Forum, virtual: November 15-18, 2021	Furthered agreement on harmonization of studies that should be conducted to demonstrate safety, effectiveness, pharmacovigilance activities, and quality of veterinary medicines.
Annual VeDDRA Meeting Series, virtual: April 7, 2021, April 12, 2021, and June 6, 2021	Hosted by the European Medicines Agency, VICH regions are invited to participate in the ongoing development of the VeDDRA vocabulary. VeDDRA is a list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products and has been adopted as a VICH standard vocabulary in VICH pharmacovigilance GL30. CVM contributes two subject matter experts to this activity. In 2021, the meeting was expanded into a series of three meetings due to the number and complexity of the change requests under review.
OIE Working Group on Antimicrobial Resistance (AMR)	Provided United States antimicrobial drug sales data (for antimicrobials intended for use in food-producing animals) to OIE database. Information from the database is used to monitor antimicrobial consumption (sales or use) and to contribute as an input for risk assessments related to antimicrobial resistance. Provided species-specific lists of approved antimicrobials to support annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use.
OIE Electronic Expert Group on Antiparasitic Resistance (EEG APR)	Work with OIE and other OIE collaborators and serve as group chair to develop guidelines on the responsible and prudent use of antiparasitic products, specifically anthelmintics used in food producing ruminant species. Activities included contributing as part of the Rapporteur Team and analyzing results of two surveys distributed to all OIE regions and making final preparations to publish the first document from this EEG. Published first document, Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species.
OIE AMU Technical Reference Group	Participate in small (virtual) working group of collaborators led by OIE, in providing input for design and future implementation of an electronic platform for OIE members to submit the antimicrobial consumption (sales or use) country data. A data dashboard is also being developed. CVM contributes one expert to this TRG.
Reviewed new animal drugs for food-producing, companion, and many aquatic animals for possible approval	Review of animal drugs for safety, efficacy, including the safety of any food produced from treated animals.
Food safety	

Title of activity	Scope
Chaired and provided technical expertise to the CODEX Committee on Residues of Veterinary Drugs in Food (CCRVDF), Virtual July 7-20, 2021	The United States delegation chaired and participated in the 25th Session of the CCRVDF. CCRVDF25 discussed many topics to further increase the availability of Codex maximum residue limits (MRLs) such as extrapolation of existing Codex MRLs to other species. The Chairperson lead preparatory webinars prior to the CCRVDF25 and successfully chaired the first virtual meeting of the CCRVDF.
Provided leadership and technical expertise to the Codex Alimentarius Commission meeting, Virtual, November & December 2021	Provided leadership and technical expertise to the Codex Alimentarius Commission meeting, Virtual, November & December 2021 Furthered discussion on the Statements of Principle and their application in the adoption of maximum residue limits. Provided background on issues arising from CCRVDF25.
Feed safety	
Title of activity	**Scope**
Chair OECD Working Party for the Safety of Novel Foods and Feeds	Continue to produce documentation of the standard values for nutrients in plants for comparison to new varieties.
Other (Name the category)	
Title of activity	**Scope**
Transatlantic Task Force on AMR (TATFAR)- various dates throughout 2021	Multiple U.S experts contributed to the work of various TATFAR activities as part of the 2021-2025 work plan.
Codex Intergovernmental Task Force on Antimicrobial Resistance- various dates throughout 2020 and 2021	The United States delegation to the Codex TFAMR continued to review and revise Codex documents, including 'Guidelines on Integrated Surveillance of Antimicrobial Resistance' and 'Code of Practice to Minimise and Contain Antimicrobial Resistance.' USCO adopted the GLIS and Code of Practice on November 10, 2021.

ToR : To propose or develop methods and procedures that facilitate harmonisation of international standards and guidelines applicable to the designated specialty

2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the surveillance and control of animal diseases, food safety or animal welfare

Proposal title	Scope/Content	Applicable area
OIE Electronic expert group on antiparasitic resistance (EEG APR)	Work with OIE and other OIE collaborators and serve as group chair to develop guidelines on the responsible and prudent use of antiparasitic products, specifically anthelmintics used in food producing ruminant species.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare
Provided leadership to and participated in the 40th VICH Steering Committee and 14th VICH Outreach Forum meeting, Virtual, November 15-18, 2021	Led the FDA delegation to the VICH Steering Committee; chaired the VICH Expert Working Groups on Safety, Pharmacovigilance, Bioequivalence, Anthelmintics, and Combination Products; participated in all VICH Expert Working Groups; and drafted the concept papers on implementation of ICH quality guideline Q8 as a VICH guideline.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare

Collaborated with the Veterinary Drugs Directorate, Health Canada to facilitate the simultaneous review of selected animal drugs	Held teleconferences and other correspondence throughout the year with reviewers to coordinate the preapproval reviews and assessments of approximately 16 animal drugs (including drugs for food producing animals), resulting in further convergence of approaches to evaluating data that support the safety, efficacy, and quality of veterinary drug registrations.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare
Collaborated with the Veterinary Drugs Directorate, Health Canada	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare
Collaborated with the European Medicines Agency	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	☐Surveillance and control of animal diseases ☒Food safety ☐Animal welfare
Collaborated with the Canadian Food Inspection Agency	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	☐Surveillance and control of animal diseases ☒Food safety ☐Animal welfare
Member of ICCF Steering Committee and Expert Working Groups	• Chaired Expert Working Group on Adsorption, Desorption, Metabolism, and Excretion Safety Assessments • Participated in Expert Working Group on Manufacturing Process and Specification • Participated in Expert Working Group on Genotoxicity Testing • Participated in Expert Working Group on Identification and Characterization of Feed Ingredients • Participated in Expert Working Group on Feed Ingredients Environmental Safety Assessment Approach	☐Surveillance and control of animal diseases ☒Food safety ☐Animal welfare
Collaborated with the United Kingdom’s Veterinary Medicines Directorate	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare
Collaborated with the Australian Pesticides and Veterinary Medicines Authority	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare
Collaborated with New Zealand’s Ministry for Primary Industries	Held teleconferences and other correspondence throughout the year on topics of mutual interest to both agencies.	☒Surveillance and control of animal diseases ☒Food safety ☒Animal welfare

ToR: To establish and maintain a network with other OIE Collaborating Centres designated for the same specialty, and should the need arise, with Collaborating Centres in other disciplines

ToR: To carry out and/or coordinate scientific and technical studies in collaboration with other centres, laboratories or organisations

3. Did your Collaborating Centre maintain a network with other OIE Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

Name of OIE CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Veterinary Medicinal Products, Agence Nationale du Médicament Vétérinaire, ANSES.	Fougères, France	☐Africa ☐Americas ☐Asia and Pacific ☒Europe ☐Middle East	Collaborated in the training of veterinary medicine regulatory personnel.
Diagnosis and Control of Animal Diseases and Related Veterinary Product Assessment in Asia, National Veterinary Assay Laboratory, Ministry of Agriculture	Japan	☐Africa ☐Americas ☒Asia and Pacific ☐Europe ☐Middle East	Collaborated in the training of veterinary medicine regulatory personnel.
Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, Department of Agriculture	Ames, Iowa, USA	☐Africa ☒Americas ☐Asia and Pacific ☐Europe ☐Middle East	Worked together to develop and establish VICH guidelines for the approval and monitoring of veterinary medicines.

4. Did your Collaborating Centre maintain a network with other OIE Collaborating Centres, Reference laboratories, or organisations in other disciplines, to coordinate scientific and technical studies?

Yes

Name of OIE CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose

Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, Department of Agriculture and National Center for Emerging and Infectious Diseases, US Centers for Disease Control and Prevention, One Health Office	USA	☐Africa ☒Americas ☐Asia and Pacific ☐Europe ☐Middle East	Coordination around One Health initiatives in support of the COVID-19 pandemic, including conducting interlaboratory comparison exercises for public and private laboratories testing animal samples and coordinating necropsies as part of in-depth case evaluation as indicated.

ToR: To place expert consultants at the disposal of the OIE.

5. Did your Collaborating Centre place expert consultants at the disposal of the OIE?

Yes

Name of expert	Kind of consultancy	Subject
Dr. Linda Walter-Grimm	Participated in the OIE Focal Points on Veterinary Products meeting (Americas) virtually April 20-21, 2021.	Overview of pharmacovigilance and training on VICH pharmacovigilance guidelines. Included training on product quality issues and how to monitor for substandard and falsified products.
Dr. Don Prater	Provided expertise to the OIE Working Group on AMR to OIE Poultry and Aquatic Animals Technical Reference ad hoc Groups.	Development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use.
Dr. Ellen Hart	Assisted other FDA/CVM members in chairing OIE's electronic expert group on antiparasitic resistance (EEG APR) (established 2019) and participate as part of the group's Rapporteur Team, drafting much of the first document on anthelmintic resistance, which was eventually published December 2021, Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species.	Develop guidelines on the responsible and prudent use of antiparasitic products.

Dr. Ellen Hart	Worked with OIE to help plan the seventh cycle of regional focal points trainings for Veterinary Services.	Regional training seminars for OIE National Focal Points are held in each OIE Region and aim to provide participants with knowledge of the commitments and responsibilities of the OIE Delegate and raise awareness about regional and global issues and concerns outside of the national context.
Dr. Aimee Phillippi-Taylor	Provided subject matter expertise, assist other FDA/CVM members in chairing OIE's electronic expert group on antiparasitic resistance (EEG APR) (established 2019), and participate as part of the group's Rapporteur Team, drafting much of the first document on anthelmintic resistance, , which was eventually published December 2021, Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species.	Develop guidelines on the responsible and prudent use of antiparasitic products.
Dr. Aimee Phillippi-Taylor	Participated in the OIE Focal Points on Veterinary Products meeting (Americas) virtually April 20-21, 2021.	The sixth cycle of focal points trainings involved a focus on antiparasitic resistance following from the recent establishment of the OIE EEG APR. Analyzed and presented results obtained from the Americas for two surveys administered as part of the OIE EEG APR, which served to educate the region on the regional status of APR and reinforce the importance of the EEG.
Dr. Anna Obrien	Provided subject matter expertise, assist other FDA/CVM members in chairing OIE's electronic expert group on antiparasitic resistance (EEG APR) (established 2019), and participate as part of the group's Rapporteur Team, drafting much of the first document on anthelmintic resistance, , which was eventually published December 2021, Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species.	Develop guidelines on the responsible and prudent use of antiparasitic products.
Dr. Susan Bright	Provided subject matter expertise for OIE Working Group on AMR and OIE AMU Technical Reference Group.	Provide U.S. contribution of antimicrobial sales and/or use data for preparation of OIE annual report and provide assistance for development of OIE electronic platform for submission of antimicrobial sales and/or use data.
Dr. Paulette Salmon	Assisted with review and collection of FDA-approved antimicrobials to assist in development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use. SME review shared with FDA rep.	Development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use.

Dr. Jen Matysczak	Assisted with review and collection of FDA-approved antimicrobials to assist in development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use. SME review shared with FDA rep.	Development of species-specific annexes of the List of Antimicrobial Agents of Veterinary Importance and review of OIE Global Database on Antimicrobial Use.

ToR: To provide, within the designated specialty, scientific and technical training to personnel from OIE Member Countries

6. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by the OIE, to personnel from OIE Member Countries?

Yes
a) Technical visits: 0
b) Seminars: 3
c) Hands-on training courses: 0
d) Internships (>1 month): 0

Type of technical training provided (a, b, c or d)	Content	Country of origin of the expert(s) provided with training	No. participants from the corresponding country
b	Participated in OIE Focal Points for Veterinary Products (Cycle VI) virtual meeting for the Americas covering pharmacovigilance and antiparasitic resistance.	Americas	66
b	Presentation at OIE's Committee for Veterinary Medicines of the Americas (CAMEVET), Virtual November 17-19th, 2021, on the importance of the human intestinal microbiome in FDA's pre-approval evaluation of drugs for food producing animals.	Americas	217
b	FDA recorded a presentation on the implementation of VICH GL 27 on antimicrobial resistance which was shared with participants in the 13th VICH Outreach Forum. Presenters also participated in a follow up webinar the following February (2/9/2021) to address questions from VICH Outreach Forum Members on the content of the recorded presentations.	United States, Japan, Europe	32

ToR: To organise and participate in scientific meetings and other activities on behalf of the OIE

7. Did your Collaborating Centre organise or participate in the organisation of scientific meetings on behalf of the OIE?

Yes

National/International	Title of event	Co-organiser	Date (mm/yy)	Location	No. Participants
International	OIE's National Focal Points for Veterinary Products Training Seminar on Veterinary Products, 6th Cycle	OIE	04/21	Americas - virtual	66

ToR: To collect, process, analyse, publish and disseminate data and information relevant to the designated specialty

8. Publication and dissemination of any information within the remit of the mandate given by the OIE that may be useful to Member Countries of the OIE

a) Articles published in peer-reviewed journals: 46

Aljahdali NH, Khajanchi BK, Weston K, Deck J, Cox J, Singh R, Gilbert J, Sanad YM, Han J, Nayak R, and Foley SL. Genotypic and Phenotypic Characterization of Incompatibility Group FIB Positive Salmonella enterica Serovar Typhimurium Isolates from Food Animal Sources. Genes (Basel). 2020 Nov 4;11(11):E1307.* https://www.doi.org/10.3390/genes11111307

Bright RA, Rankin SK, Dowdy K, Blok SV, Bright SJ, Palmer LM. Finding Potential Adverse Events in the Unstructured Text of Electronic Health Care Records: Development of the Shakespeare Method. JMIRx Med. 2021;2(3): e27017.
https://www.doi.org/10.2196/27017

Casse SE, Yanong RPE, Pouder DB, Rodreguez C, Mylniczenko N, Thompson PM, Stilwell NK, Heym KJ, Harmon T, and Stacy NI. Reference Intervals for Blood Analytes of Adult Aquarium-Housed Russian Sturgeon Acipenser guledenstaedtii. Journal of Aquatic Animal Health. 2021;33(1)33-43.
https://doi.org/10.1002/AAH.10116.

Chiesa OA , Gonzales R, Kouneski A, Lewandowski A, Rotstein D, Myers MJ. Minimally Invasive Ultrasound-Guided Technique for Central Venous Catheterization Via the External Jugular Vein in Pigs. American Journal of Veterinary Research. 2021 Sep;82(9):760-769.
https://doi.org/10.2460/ajvr.82.9.760

Commichaux S, Javkar K, Ramachandran P, Nagarajan N, Bertrand D, Chen Y, Reed E, Gonzalez-Escalona N, Strain E, Rand H, Pop M, Ottesen A. Evaluating the Accuracy of Listeria monocytogenes Assemblies from Quasimetagenomic Samples Using Long and Short Reads. BMC Genomics. 2021 May; 22(1):389.
https://doi.org/10.1186/s12864-021-07702-2

Daniel D, Vasseur P, Jacobs A, Aguila MC, Ertych N, Jacobs MN. Integration of Epigenetic Mechanisms into Non-Genotoxic Carcinogenicity Hazard Assessment: Focus on DNA Methylation and Histone Modifications. International Journal of Molecular Sciences. 2021; 22: 10969.
https://doi.org/10.3390/ijms222010969

Deng K, Uhlig S, Ip HS, Lea Killian M, Goodman LB, Nemser S, Ulaszek J, Pickens S, Newkirk R, Kmet M, Frost K, Hettwer K, Colson B, Nichani K, Schlierf A, Tkachenko A, Reddy R, Reimschuessel R. Interlaboratory Comparison of SARS-CoV2 Molecular Detection Assays in Use by U.S. Veterinary Diagnostic Laboratories. Journal of Veterinary Diagnostic Investigation. 2021 Nov;33(6):1039-1051.
https://doi.org/10.1177/10406387211029913

Domesle KJ, Young SR, Ge B. Rapid Screening for Salmonella in Raw Pet Food by Loop-Mediated Isothermal Amplification. Journal of Food Protection. 2021 Mar; 84(3):399-407.
https://doi.org/10.4315/JFP-20-365

Epstein LR, Lee SS, Miller MF, Lombardi HA. CRISPR, Animals, and FDA Oversight: Building a Path to Success. Proceedings of the National Academy of Sciences. 2021;118(0) e2003831117. https://doi.org/10.1073/pnas.2004831117

Fu Y, M'ikanatha NM, Whitehouse CA, Tate H, Ottesen A, Lorch JM, Blehert DS, Berlowski-Zier B, Dudley EG. Low Occurrence of Multi-Antimicrobial and Heavy Metal Resistance in Salmonella enterica from Wild Birds in the United States. Environmental Microbiology. 2021 Dec 12. https://doi.org/10.1111/1462-2920.15865

Girard L, Herath K, Escobar H, Reimschuessel R, Ceric O, Jayasuriya H. Development of UHPLC/Q-TOF Analysis Method to Screen Glycerin for Direct Detection of Process Contaminants 3-Monochloropropane-1,2-diol Esters (3-MCPDEs) and Glycidyl Esters (GEs). Molecules. 2021 Apr 26(9):449. https://doi.org/10.3390/molecules26092449

Goyal D, Francois Watkins LK, Montgomery MP, Bodeis Jones SM, Caidi H, and Friedman CR. Antimicrobial Susceptibility Testing and Successful Treatment of Hospitalised Patients with Extensively Drug-Resistant (XDR) Campylobacter jejuni Infections Linked to a Pet Store Puppy Outbreak. Journal of Global Antimicrobial Resistance. 2021 Sep; 26:84-90. https://doi.org/10.1016/j.jgar.2021.04.029

Gu G, Strawn LK, Ottesen AR, Ramachandran P, Reed EA, Zheng J, Boyer RR, Rideout SL. Correlation of Salmonella enterica and Listeria monocytogenes in Irrigation Water to Environmental Factors, Fecal Indicators, and Bacterial Communities. Frontiers in Microbiology. 2021 Jan; 11: 557289. https://doi.org/10.3389/fmicb.2020.557289

Handy SM, Pawar RS, Ottesen AR, Ramachandran P, Sagi S, Zhang N, Hsu E, Erickson DL. HPLC-UV, Metabarcoding and Genome Skims of Botanical Dietary Supplements: A Case Study in Echinacea. Planta Medica. 2021 Apr; 87(4):314-324. https://doi.org/10.1055/a-1336-1685

Harrill JA, Viant MR, Yauk CL, Sachana M, Gant TW, Auerbach SS, Berger RD, Bouhifd M, O'Brien J, Burgoon L, Caiment F, Carpi D, Chen T, Chorley BN, Colbourne J, Ekman DR, Faulhammer F, Gribaldo L, Hilton GM, Jones SP, Kende A, Lawson TN, Leite SB, Leonards PEG, Luijten M, Martin A, Moussa L, Rudaz S, Schmitz O, Sobanski T, Strauss V, Vaccari M, Vijay V, Weber RJM, Williams AJ, Wiliams A, Thomas RS, and Whelan M. Progress Towards an OECD Reporting Framework for Transcriptomics and Metabolomics in Regulatory Toxicology. Regulatory Toxicology and Pharmacology. 2021 Oct;125:105010. https://www.doi.org/10.1016/j.yrtph.2021.105020

Harrison L, Mukherjee S, Hsu CH, Young S, Strain E, Zhang Q, Tillman GE, Morales C, Haro J, and Zhao S. Genome MLST for Source Attribution of Campylobacter coli. Frontiers in Microbiology. 2021 Jul; 12:1-10. https://doi.org/10.3389/fmicb.2021.703890

Kopper JJ, Iennarella-Servantez C, Jergens AE, Sahoo DK, Guillot E, Bourgois-Moche A, Martinez MN, Allenspach K and Mochel JP (2021) Harnessing the Biology of Canine Intestinal Organoids to Heighten Understanding of Inflammatory Bowel Disease Pathogenesis and Accelerate Drug Discovery: A One Health Approach. Frontiers in Toxicology. 2021 Nov; 3:773953. https://doi.org/10.3389/ftox.2021.773953

Li C, Tyson GH, Hsu CH, Harrison L, Strain E, Tran TT, Tillman GE, Dessai U, McDermott PF, and Zhao S. Long-read Sequencing Reveals Evolution and Acquisition of Antimicrobial Resistance and Virulence Genes in Salmonella enterica. Frontiers in Microbiology. 2021 Nov; 12: 1-14. https://doi.org/10.3389/fmicb.2021.777817

Liu Z, Screven R, Yu D, Boxer L, Myers MJ, Han J, Devireddy LR. 2021. Microfluidic Separation of Canine Adipose-Derived Mesenchymal Stromal Cells. Tissue Engineering Part-C. 2021 Aug;27(8):445-461. https://doi.org/10.1089/ten.TEC.2021.0082

Martinez MN, Mochel JP, Neuhoff S, Pade D. Comparison of Canine and Human Physiological Factors: Understanding Interspecies Differences that Impact Drug Pharmacokinetics. The AAPS Journal. 2021 Apr;23(3):59-75. https://doi.org/10.1208/S12248-021-00590-0

Martinez MN, Soback S. An Introduction to the JVPT Special Issue on Antimicrobial Drugs. Journal of Veterinary

Pharmacology and Therapeutics. 2021 Mar;44(2):133-136.
https://doi.org/10.1111/jvp.12908

Mazengia E, Meschke J, Greeson K, Zhao S, Abbott J, Eckmann K, Tate H, Huang X, and Samadpour M. Determining the DNA Fingerprinting Profiles of Salmonella Isolates from Raw Poultry Meats and Human Clinical Samples from the Same Geographic Area Using Pulsed-Field Gel Electrophoresis. Journal of Food Protection. 2021 Jul; 84(7):1265-1274.
https://doi.org/10.4315/JFP-20-421

McDermott PF and Davis JJ. Predicting Antimicrobial Susceptibility from the Bacterial Genome: A New Paradigm for One Health Resistance Monitoring. Invited article, Journal of Veterinary Pharmacology and Therapeutics. 2021 Mar;44(2):223-237.
https://doi.org/10.1111/jvp.12913

Miller RA, Salmon P, Sharkey M. Approaches to Developing Judicious Uses of Veterinary Antibacterial Drugs. Journal of Veterinary Pharmacology and Therapeutics. 2021 Mar;44(2):201-206.
https://doi.org/10.1111/jvp.12828

Mohan N, Luo X, Shen Y, Olson Z, Agrawal A, Endo Y, Rotstein DS, Pelosof LC, Wu WJ. A Novel Bispecific Antibody Targeting EGFR and VEGFR2 Is Effective against Triple Negative Breast Cancer via Multiple Mechanisms of Action. Cancers (Basel). 2021 Mar 1;13(5):1027.
https:///www.doi.org/10.3390/cancers13051027

Myers MJ, Howard KD, Kawalek, JC. Pharmacokinetic Comparison of Six Anthelmintics in Sheep, Goats and Cattle. Journal of Veterinary Pharmacology and Therapeutics. 2021 Jan; 44(1):58-67.
https://doi.org/10.1111/jvp.12897

Nemser S, Lindemann S, Chen Y, Lopez S, Pickens S, Ulaszek J, Kmet M, Powers C, Ensley S, Schrunk D, Rumbeiha W, Tkachenko A, Guag J, Ceric O, Jones J, Reimschuessel R, Reddy R. A Review of Proficiency Exercises Offered by the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) and Moffett Proficiency Testing Laboratory from 2012 to 2018. Accreditation and Quality Assurance. 2021 June;26:143-156.
https://doi.org/10.1007/s00769-021-01471-x

Peloquin SK, Rotstein DS, Jones JL, Guag J, Carey L, Palmer LA, Wolf K, Burkholder W, Hodges A, Payne L, Reimschuessel R. Presumed Choline Chloride Toxicosis in Cats With Positive Ethylene Glycol Tests After Consuming a Recalled Cat Food. Topics in Companion Animal Medicine. 2021 Aug;44:100548.
https://doi.org/10.1016/j.tcam.2021.100548

Pineiro SA, Cerniglia CE. Antimicrobial Drug Residues in Animal-Derived Foods: Potential Impact on the Human Intestinal Microbiome. Journal of Veterinary Pharmacology and Therapeutics. 2021 Mar;44(2)215-222.
https://doi.org/10.1111/jvp.12892

Prescott JF, Martinez MN, Turnidge J, and Page SW. The Publication of Studies Involving the Use of Human Critically Important Antimicrobial Agents in Veterinary Species. Journal of Veterinary Pharmacology and Therapeutics. 2021 Nov;44(6):986-989.
https://doi.org/10.1111/jvp.13005

Reed E, Sanderson R, Sanderson B, Ramachandran P, Commichaux S, Brown E, Zheng J, Strain E, Ottesen A. Water Microbiota from a Commercial Alfalfa Sprout Crop over 4 Days of Growth. Microbiology Resource Announcements. 2021 Jan;10(2): e00906-20.
https://doi.org/10.1128/MRA.00906-20

Rotstein D. From Precision Medicine to Pathology of Unconventional Animal Models to Molecular Pathology to COVID-19: Award-Winning Presentations at the Virtual 2021 ACVP and ASVCP Concurrent Annual Meeting. Veterinary Pathology. 2021 Sep;58(5):762-763.
https://www.doi.org/10.1177/03009858211022707

Rotstein D, Jones JL, Buchweitz J, Refsal KR, Wilson R, Yanes EG, Heitkemper D, Edwards E, Post L, Palmer LA, Carey L, Wolf K, Burkholder W, Ceric O, Glover M, Hodges A, Kemppainen RJ, Lambkin S, Lovell R, Nemser S, Wilkinson C, Reimschuessel R. Pet Food-Associated Dietary Exogenous Thyrotoxicosis: Retrospective Study (2016-2018) and Clinical Considerations. Topics in Companion Animal Medicine. 2021 Jun;43:100521.
https://doi.org/10.1016/j.tcam.2021.100521

Swain T, Deaver CM, Lewandowski A, and Myers MJ. Lipopolysaccharide (LPS) Induced Inflammatory Changes to Differentially Expressed miRNAs of the Host Inflammatory Response. Veterinary Immunology and Immunopathology. 2021 Jul;237:110267.
https://doi.org/10.1016/j.vetimm.2021.110267

Taghvaei M, Tonyali B, Sommers C, Ceric O, Linghu Z, Smith JS, Yucel U. Formation Kinetics of Radiolytic Lipid Products in Model Food–Lipid Systems with Gamma Irradiation. Journal of the American Oil Chemists' Society. 2021 Jul;98(7):737-746.
https://doi.org/10.1002/aocs.12513.

Tate H, Li C, Nyirabahizi E, Tyson GH, Zhao S, Rice-Trujillo C, Bodeis Jones S, Ayers A, M'ikanatha NM, Hanna S, Ruesch L, Cavanaugh ME, Laksanalamai P, Mingle L, Matzinger SR, and McDermott PF. A National Antimicrobial Resistance Monitoring System Survey of Antimicrobial-Resistant Foodborne Bacteria Isolated from Retail Veal in the United States. Journal of Food Protection. 2021 Oct;84(10):1749-1759.
https://doi.org/10.4315/JFP-21-005

Tkachenko A, Benson K, Mostrom M, Guag J, Reimschuessel R, and Webb B. Extensive Evaluation Via Blinded Testing of an UHPLC-MS/MS Method for Quantitation of Ten Ergot Alkaloids in Rye and Wheat Grains. Journal of AOAC International. 2021 Jun; 104(3):546-554.
https://doi.org/10.1093/jaoacint/qsaa173

Tyson GH, Ceric O, Guag J, Nemser S, Borenstein S, Slavic D, Lippert S, McDowell R, Krishnamurthy A, Korosec S, Friday C, Pople N, Saab ME, Fairbrother JH, Janelle I, McMillan D, Bommineni YR, Simon D, Mohan S, Sanchez S, Phillips A, Bartlett P, Naikare H, Watson C, Sahin O, Stinman C, Wang L, Maddox C, DeShambo V, Hendrix K, Lubelski D, Burklund A, Lubbers B, Reed D, Jenkins T, Erol E, Patel M, Locke S, Fortner J, Peak L, Balasuriya U, Mani R, Kettler N, Olsen K, Zhang S, Shen Z, Landinez MP, Thornton JK, Thachil A, Byrd M, Jacob M, Krogh D, Webb B, Schaan L, Patil A, Dasgupta S, Mann S, Goodman LB, Franklin-Guild RJ, Anderson RR, Mitchell PK, Cronk BD, Aprea M, Cui J, Jurkovic D, Prarat M, Zhang Y, Shiplett K, Campos DD, Rubio JVB, Ramanchandran A, Talent S, Tewari D, Thirumalapura N, Kelly D, Barnhart D, Hall L, Rankin S, Dietrich J, Cole S, Scaria J, Antony L, Lawhon SD, Wu J, McCoy C, Dietz K, Wolking R, Alexander T, Burbick C, and Reimschuessel R. Genomics Accurately Predicts Antimicrobial Resistance in Staphylococcus pseudintermedius Collected as Part of Vet-LIRN Resistance Monitoring. Veterinary Microbiology. 2021 Mar;254:109006.
https://doi.org/10.1016/j.vetmic.2021.109006

Tyson GH, Li C, Harrison LB, Martin G, Hsu CH, Tate H, Tran TT, Strain E, and Zhao S. A Multidrug-Resistant Salmonella infantis Clone Is Spreading and Recombining in the United States. Microbial Drug Resistance. 2021 Jun;27(6):792-799.
https://doi.org/10.1089/mdr.2020.0389

Vudathala D, Cummings M, Tkachenko A, Guag J, Reimschuessel R, and Murphy L. A Lateral Flow Method for Aflatoxin B1 in Dry Dog Food: An Inter-Laboratory Trial. Journal of AOAC International. 2021 Jun;104(3):555-561.
https://doi.org/10.1093/jaoacint/qsaa175

Wallis A, Gu G, Ramachandran P, Reed E, Ottesen A, Nou X, and Cox KD. Endophytic Bacterial Communities in Apple Leaves Are Minimally Impacted by Streptomycin Use for Fire Blight Management. Phytobiomes Journal. 2021 Apr;5(3).
https://doi.org/10.1094/PBIOMES-11-20-0081-R

Wallis A, Yannuzzi IM, Choi M-W, Spafford J, Fenn M, Ramachandran P, Timme R, Pettengill JB, Cagle R, Ottesen A, and Cox KD. Investigating the Distribution of Strains of Erwinia amylovora and Streptomycin Resistance in Apple Orchards in New York Using Clustered Regularly Interspaced Short Palindromic Repeat Profiles: A 6-Year Follow-Up. Plant Disease. 2021 Nov 24.
https://doi.org/10.1094/PDIS-12-20-2585-RE

Williams MS, Ebel ED, and Nyirabahizi E. Comparative History of Campylobacter Contamination on Chicken Meat and Campylobacteriosis Cases in the United States: 1994-2018. International Journal of Food Microbiology. 2021 Mar;342: 109075.
https://doi.org/10.1016/j.ijfoodmicro.2021.109075

Yin X, M'ikanatha NM, Nyirabahizi E, McDermott PF, Tate H. Antimicrobial Resistance in Non-Typhoidal Salmonella from Retail Poultry Meat by Antibiotic Usage-Related Production Claims - United States, 2008-2017. International Journal of Food Microbiology. 2021 Mar; 342:109044.

https://doi.org/10.1016/j.ijfoodmicro.2021.109044

Youngbeom A, Jung JY, Kweon O, Veach BT, Khare S, Gokulan K, Pineiro SA, Cerniglia, CE. Impact of Chronic Tetracycline Exposure on Human Intestinal Microbiota in a Continuous Flow Bioreactor Model. Antibiotics. 2021 Jul;10(8): 886.
https://www.doi.org/10.3390/antibiotics10080886

Zheng J, Reed E, Ramachandran P, Ottesen A, Brown EW, and Wang Y. Taxonomic and Functional Shifts in the Sprout Spent Irrigation Water Microbiome in Response to Salmonella Contamination of Alfalfa Seeds. Applied and Environmental Microbiology. 2021 Jan;87(3): e01811-20.
https://doi.org/10.1128/AEM.01811-20

b) International conferences: 15
International Association for Food Protection (IAFP) Annual meeting, 07/18/2021 – Shenia Young – Phenotypic and Genotypic Characterization of Salmonella Resistance within the U.S. Food and Drug Administration's Foods Program

World Microbe Forum (ASM Microbe) 2021
• Lucas Harrison – Identification of Conserved Genetic Elements among IncA/C Plasmids from 18 Bacterial Genera, 06/20/2021
• Lucas Harrison – Core Genome MLST for Source Attribution of Campylobacter coli, 06/20/2021
• Cong Li – Long-read sequencing reveals evolution of antimicrobial resistance and virulence genes of Salmonella enterica isolated from food animal sources, 06/20/2021
• Errol Strain – Machine Learning for MIC Predictions using Whole-Genome Sequencing for FDA NARMS, 06/18/2021
• Heather Tate – Genomic Diversity of Salmonella Kentucky Isolated from Humans, Food, and Animal Sources in the United States, 06/20/2021
• Gregory Tyson – Use of large-scale genomics to identify the role of animals and foods as potential sources of ExPEC causing human illnesses, 06/20/2021

European Medical Authority (EMA) Veterinary Big Data Stakeholder Forum, 06/01/2020
• Errol Strain – Big Data at the FDA Center for Veterinary Medicine
• Hesha Duggirala – Represented FDA CVM for roundtable discussion

Women in Statistics and Data Science Conference, 04/01/2021 – Epiphanie Nyirabahizi – Evaluation of Salmonella resistance trends based on MICs mixture distributions in NARMS retail meat data

The Use of Genomics in One Health AMR Surveillance: The Experience of the US National Antimicrobial Resistance Monitoring System. Science meets Policy conference: Modern technologies to enable response to crises: Next Generation Sequencing to tackle food-borne diseases in the EU. Sep 25, 2020. Istituto Superiore di Sanità, Rome, Italy. Patrick McDermott.

Parental Drug Association (PDA) Aseptic Animal Health Conference, October 2021
• Marianne Martinson - The One Health Initiative in the U.S. and the rest of the world, too. What does it mean and how can you get involved?
• Jeanette Gonzalez - Resistant Campylobacter outbreak linked to contact with puppies: a case for good antimicrobial stewardship practices"
• Peter Bryk – One Health Strategies to Combat Emerging Infectious Diseases
• Kate Huebner - Regulatory Oversight of Animal Biologics and Animal Drugs in the United States

c) National conferences: 7
27th Annual Aquaculture Drug Approval Coordination Workshop, 07/27/2021 – Elliott Kittel – FDA Phish-Pharm Literature Database: Overview, Demonstration, and 2021 Release Update

NARMS retail meat program, 04/26/2021 – Shaohua Zhao – Implementation of Whole Genome Sequencing in the NARMS Retail Meat Program

University of Missouri College of Veterinary Medicine, 03/15/2021 – Jennifer Jones – Investigating Possible Foodborne Illness in Animals

Presidential Advisory Council to Combat Antimicrobial Resistant Bacteria (PACCARB). Dec 1, 2021. Patrick McDermott - "NARMS and the Evolution of One Health Surveillance"

2021 USAHA/AAVLD Annual Meeting – Vet-LIRN Update USAHA/AAVLD Committee on Food and Feed Safety, October 23, 2021

American Veterinary Medical Association Annual Convention (virtual), August 2020, presented on veterinary drug compounding and regulation of cannabidiol (CBD)

National Academy Sciences Engineering and Medicine (NASEM), February 2021 – Kate Huebner and Danielle Sholly - One Health Approach to Outbreak Preparedness- FDA and Response to African Swine Fever

d) Other
(Provide website address or link to appropriate information): 3
Published Databases
Animal and Veterinary API Endpoints and Dataset: Adverse Event Reports [Internet]. White Oak (MD): U.S. Food and Drug Administration, Center for Veterinary Medicine. 1987- [cited 2020 Dec 15]. Available from: https://open.fda.gov/apis/animalandveterinary/event/

Book Chapters
Grim CJ and Whitehouse CA. 2021. Chapter 13: Aeromonas and Plesiomonas. In: Foodborne Infections and Intoxications (Fifth Edition) 2021: 237-252.
https://doi.org/10.1016/B978-0-12-819519-2.00026-8

Technical reports / methods
Strain E, Kabera C, McDermott PF on behalf of NARMS. NARMS Retail Meat Testing Interim Data Update: Multidrug-Resistant (MDR) Salmonella I 4,[5],12:i:-. May 2021.
Available at: NARMS Interim Data Updates | FDA.

9. Additional comments regarding your report: