

Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals





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Preliminary Summary Report

Prepared by the Reagan-Udall Foundation for the FDA For Food and Drug Administration’s Center of Veterinary Medicine

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Executive Summary

[Antimicrobial resistance](#) (AMR) is recognized as a growing global threat requiring action in product research and development as well as fostering antimicrobial stewardship in human and animal health. Currently, limited data are available about the relationship between AMR and antimicrobial use data in food-producing animals (one component of AMR response). As part of ongoing activity to better understand this relationship, the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) engaged the Reagan-Udall Foundation for the FDA (FDA Foundation) to facilitate conversations with relevant stakeholders to assess the feasibility of creating a public-private partnership to develop an antimicrobial drug use data repository to foster antimicrobial stewardship in food-producing animals.

The FDA Foundation spoke to 30 stakeholders, including food-producing animal trade associations, researchers and academics, consumer advocacy groups, and government agencies. After a robust discussion, participants identified the following as a consensus objective for a potential public-private partnership:

Gathering antimicrobial use data in food-producing animals to foster antimicrobial stewardship and animal health and welfare.

The following key themes emerged from the discussion:

- Antimicrobial sales and distribution data and antimicrobial use data are not the same.
- Context, such as the number, size, species of animals, and indication, is essential to understand antimicrobial use in food-producing animals.
- Collecting standardized data across species and routes of administration is challenging.
- Each food-producing species or food commodity requires unique considerations and species data should not be directly compared to other species.
- Clear data access and privacy protection are essential to build and maintain mutual trust among public and private partners.

The FDA Foundation will use these themes to inform the principles for a potential public-private partnership.

Background

[Antimicrobial resistance](#) (AMR) is recognized as a growing global threat requiring action in product research and development and fostering stewardship of antimicrobial use in human and animal health. AMR can be viewed through the [One Health](#)^{*} approach, which recognizes that the health of humans, animals, and the environment are interconnected. The relevant regulatory agencies of the U.S. government have relatively limited data on the use of antimicrobials in food-producing animals, and the relationship between antimicrobial use and AMR in food-producing animals.

Currently, FDA collects data on estimates of sales of antimicrobial drugs by major food-producing species through the section 105 of the [Animal Drug User Fee Amendments of 2008 \(ADUFA\)](#). [Section 105](#) amendment to section 512 of the [Federal Food, Drug, and Cosmetic Act](#) requires sponsors of approved and conditionally-approved applications for new animal drugs containing an antimicrobial active ingredient to submit an annual report to the FDA on the amount of each such ingredient in the drug that is sold or distributed for use, including information on any distributor-labeled product. In 2016, FDA issued a final rule to obtain more detailed information about antimicrobials sold or distributed for use in food-producing animals by including estimates of sales data by species. Since that time, each sales and distribution report include a species-specific estimate of the percentage of product from three or more sponsors that was sold or distributed domestically in the reporting year for use in any of the major food producing animal species categories, but only for such species that appear on the approved label. FDA publishes annual summary reports of the sales and distribution data. Sales over time is an indicator of market trends related to these products; however, it does not consider additional information including actual use data, animal demographics, animal health data, and data on AMR. There is no statutory requirement for collection of antimicrobial use data (i.e., whether the purchased product—as represented in the sales report—is actually administered to any animals).

Since 2016, FDA has funded two cooperative agreements to pilot on-farm antimicrobial use data collection methodologies in food producing animals. These efforts are intended to provide part of the baseline information on antimicrobial use practices in the four major food-producing animal groups (cattle, swine, chickens, and turkeys).

In addition to analyzing antimicrobial sales data, FDA monitors AMR trends through the [National Antimicrobial Resistance Monitoring System](#) (NARMS).[†] FDA initiated discussions with USDA and CDC to expand the scope of NARMS and strengthen data collection capabilities. USDA's [National Animal Health Monitoring System \(NAHMS\)](#) also reports AMU data for swine and feedlot cattle. However, these reports focus on specific production classes and do not evaluate the antimicrobial use throughout the

^{*}The [CDC defines One Health](#) as “a collaborative, multisectoral, and transdisciplinary approach — working at the local, regional, national, and global levels — with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.” Common issues for One Health include antimicrobial resistance, zoonotic diseases, food safety and food security, vector-borne diseases, environmental contamination, and other health threats shared by people, animals, and the environment. Antimicrobial resistance has the potential to impact human health at all stages of life as well as the health care, veterinary, and agriculture industries.

[†]NARMS is a collaboration between state and local public health departments and universities, FDA, CDC, and USDA. It is a “national public health surveillance system that tracks changes in the antimicrobial susceptibility of enteric (intestinal) bacteria found in ill people (CDC), retail meats (FDA), and food animals (USDA) in the United States.”

lifetime of the animal. While these efforts will provide additional context, they are not expected to generate real-world data (RWD) about antimicrobial use in food-producing animals. Access to such RWD regarding antimicrobial use in animals may help veterinarians, animal producers, and federal agencies track and understand use trends as well as assess efforts designed to maintain the effectiveness of antimicrobials for both humans and animals.

To help address current gaps in data, FDA asked the FDA Foundation to explore the feasibility of creating a public-private partnership to build a data repository to track and monitor the antimicrobial drug use in major food-producing animals. Figure 1 shows a few structures for such a partnership under consideration.

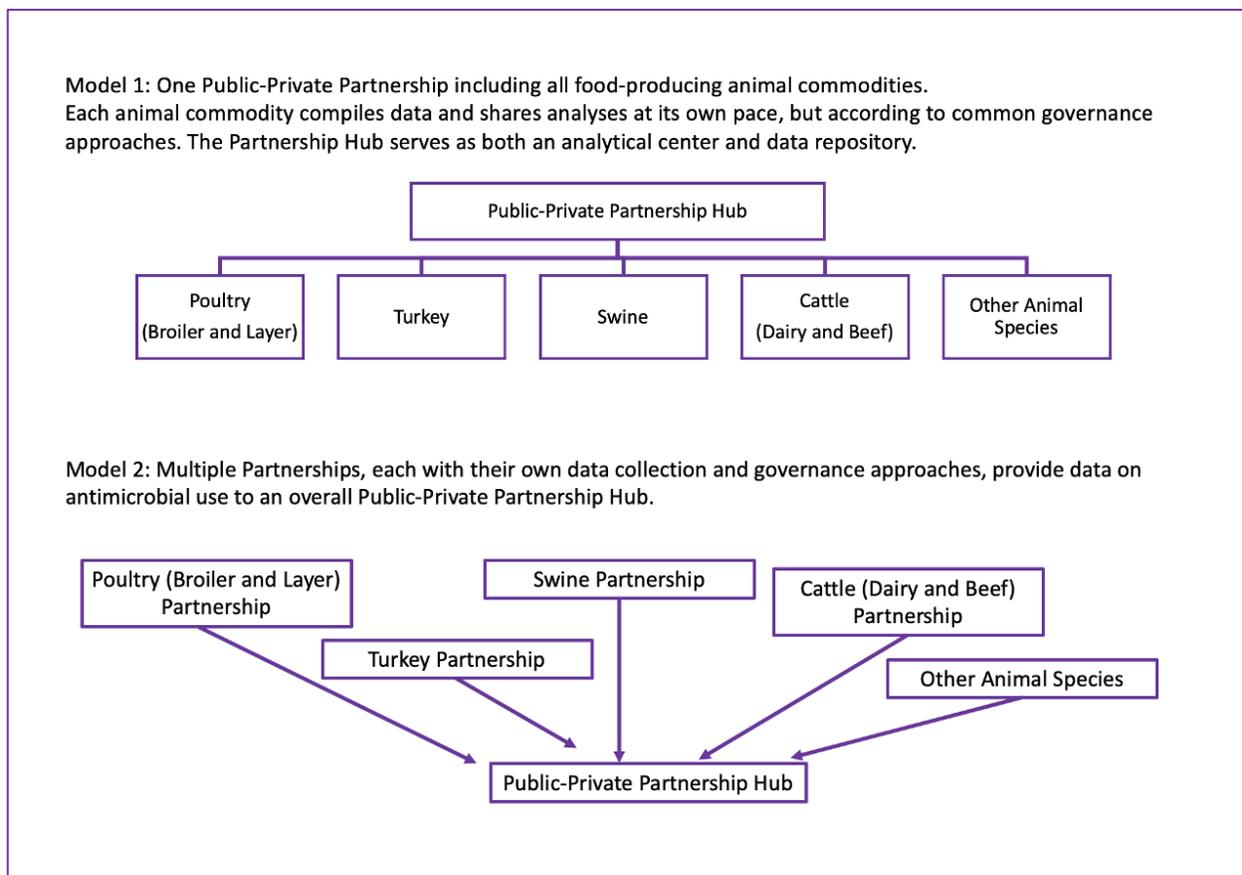


Figure 1: Sample public-private partnership structures.

Such a partnership could generate data and analyses for a variety of stakeholders, including other federal agencies and policymakers, researchers, veterinarians, academia, consumer advocacy groups, industry, and the public. To develop a robust and sustainable RWD system, recognizing that the goal is not to reduce AMU to zero use (which would result in animals untreated for addressable conditions), it is essential to engage stakeholders who are involved in all aspects of the food-producing animal supply chain, including feed manufacturers, drug sponsors, producers, veterinarians, and others who generate and own the relevant data.

Stakeholder Meetings and Virtual Roundtable

To understand the feasibility of setting up a public-private partnership to collect antimicrobial use in food-producing species, the FDA Foundation conducted several one-on-one and small group conversations with key stakeholders. Discussions focused on the potential purpose, benefits, limitations, and challenges to collecting and sharing trends from those data. Stakeholders provided insights into the landscape of efforts to collect and analyze antimicrobial use data as well as the benefits and challenges for those efforts. The conversations led to key themes that informed the initial version of the draft objective and principles to support establishing a potential public-private partnership to support the tracking and monitoring of antimicrobial use in food-producing animals.

The FDA Foundation met with 30 stakeholders with expertise in the use of antimicrobials in the food-producing animal supply chain. These stakeholders, identified with input from FDA, provided insights into animal movements within the different animal commodities through animal production; how antimicrobial use data is collected and maintained; and the feasibility of a potential of a public-private partnership. Table 1 summarizes the categories of stakeholders who participated in small group conversations and the roundtable discussions.[‡]

Organization Type	Count
Research/Academia and Consumer Groups	12
Trade Organizations for Producers	8
Veterinarians and Clinical Supporting Companies	5
Government Agencies	4
Animal Drug Manufacturer	1

Virtual Roundtable

In late March 2022, the FDA Foundation held an in-depth virtual roundtable to discuss the feasibility of creating a public-private partnership to support the tracking and monitoring of antimicrobial use in food-producing animals of antimicrobial drug use in food-producing animals.[§] Participants included organizational and individual stakeholders who are responsible for the generation, collection, storage, and maintenance of primary on-farm data related to antimicrobial use in food-producing animals. The discussion focused on the potential purpose, benefits, limitations, and challenges to collecting and sharing findings from those data to a variety of interested parties, including government entities, researchers/academia, consumer advocacy groups, industry, and the public. Participants discussed the objective and draft principles for a public-private partnership.

[‡] A full list of stakeholder organization names is included in [Appendix II](#).

[§] The agenda for the roundtable meeting is included in [Appendix I](#).

Objective of a Public-Private Partnership

While discussing the objective of the partnership, participants noted that a data repository could be useful and improve efficiency by consolidating existing efforts to collect antimicrobial use data. A data repository facilitated through a public-private partnership could provide additional assurances of data security and integrity. The partnership could present an opportunity for collaboration among different commodities, as well establish standardized methods for data collection across commodities. Summary reports could provide producers with benchmark data to understand antimicrobial use in comparison to national trends and make data-driven decisions to support improved antimicrobial stewardship. Overall, a potential partnership could promote antimicrobial stewardship efforts benefiting animal welfare and would support a One Health approach to understanding antimicrobial use and AMR.

After a robust discussion, the overall objective of a potential partnership is summarized as:

Gathering antimicrobial use data in food-producing animals to foster antimicrobial stewardship and animal health and welfare.

Key Themes

In addition to consensus about the goals of a public-private partnership, key themes emerged from the conversations and roundtable discussion. They are summarized in the sections below.

Antimicrobial sales and distribution data and antimicrobial use data are not the same.

In the absence of accurate antimicrobial use data, sales and distribution data are often incorrectly used as a proxy for use data, even though sales do not represent actual use of the products. Sales and distribution data represent the volume of antimicrobials sold into distribution, and thus represent the maximum amount of product that could have been administered to animals. (For example, veterinarians and animal producers may purchase drugs, but may not actually administer them to animals, or they may be administered in later years.) The data do not represent the amount of antimicrobials that were ultimately administered to any animals, and for what indication (e.g., to treat an active infection or risk of infection). Without adequate collection of antimicrobial use data, including context for use such as disease indication, an accurate picture of use cannot be generated, and thus is not available to optimize antimicrobial stewardship or evaluate associations between antimicrobial use and AMR.

Context, such as the number, size, species of animals, and indication, is essential to understand antimicrobial use in food-producing animals.

Another of the challenges mentioned throughout stakeholder conversations is the risk of data being shared broadly without providing sufficient context. Providing context with aggregated use data supports accurate interpretation and reduces the potential for misuse or misrepresentation of data. Stakeholders highlighted that contextual information, such as how and when data are collected, can provide a clearer understanding of drivers of antimicrobial stewardship. Without appropriate context, the public may associate “high” use of antimicrobials with “bad”, and similarly associate “low” use of antimicrobials with “good.” Such overly simplistic interpretations of antimicrobial use data do not account for the relative potency of different antimicrobials or external factors that impact use, such as baseline animal disease or external factors impacting on-farm use. For example, an outbreak of a disease among the population of a specific species might necessitate a substantial increase in the amount of a specific antimicrobials used in that time period. Furthermore, the duration of therapeutic antimicrobials often differs by species and drugs. The indication for antimicrobial use is an additional

data point required to provide additional context. Another important variable is the demographic data, for example, animal population size, farm, lot, production category, etc., since these factors vary by species. Additional research is needed to understand which variables are essential for a potential RWD repository.

Collecting standardized data across species and routes of administration will be challenging. Heterogeneity of animal production classes and farming systems exist both among and within food-producing animal species. These differences impact whether and how antimicrobial use data are collected. Many farms, such as smaller-scale farms, may rely on paper records regarding antimicrobial use and those paper records may not move with the animals. Paper records also pose challenges for electronic reporting and interoperability. Data elements such as weights, dosage of antimicrobial given, name of antimicrobial given, and route of administration may not be measured or recorded consistently across farms of the same species or across the different species. For example, farmers might have different methods for estimating animals' weights or might record estimated weights in different unit (e.g., pounds vs. kilograms). Additionally, if an electronic health record system is used, then there could be challenges navigating different types of health record platforms. The issues of lack of data standardization, record system interoperability, and inconsistent or missing data present significant challenges for setting quality metrics or benchmarking certain measures for comparison.

Additionally, stakeholders stated that there may be a need for encouragement for collecting standardized data. Incentivizing through benchmarking methods or monetary methods may be required. This could provide stakeholders with a reward for collecting data needed to foster antimicrobial stewardship.

Many stakeholders also emphasized the importance of providing transparency of methodologies for data collection and standardization. Establishing methodologies for how the data are collected, reported, transformed, and analyzed prior to collecting such data is also very important factor. However, when establishing standardized methodologies, one must recognize that not all commodities are the same and this is one of the key challenges identified.

Each food-producing species or food commodity requires unique considerations and species-specific data should not be directly compared to other species.

During the roundtable discussion, comments underscored that each commodity requires the capture and analysis of different data elements; therefore, each commodity needs to be viewed with a different lens.

The movement of animals throughout their productive life is different for each commodity. The poultry sector, including chickens and turkeys, for example, is more vertically integrated than other sectors. In most cases, a broiler chicken will stay on one farm from birth until slaughter, while layer chicken, turkey, swine, and cattle will travel across different farms. For broiler chickens, layer chickens, turkey, and swine, there are commonly production companies that provide veterinarian services to farms. Therefore, most antimicrobials will be prescribed and administered through the production companies. This provides an opportunity to capture antimicrobial use data from the companies. For cattle, production companies are not as involved in providing veterinary services. Dairy and beef cattle more commonly have independent veterinarians that provide veterinary services. These services can be provided at any stage during the animal's life which present many opportunities to capture AMU data.

Even though data are collected at the farm level, those data may not move as the animal cycles through different farms. Different commodities generate and collect data in different ways that may require different approaches and methodologies for capturing antimicrobial use data. Therefore, differences between animal commodities needs to be considered when establishing an effective public-private partnership or partnership(s) and data repository.

Additionally, different production models exist between or within commodities. Many larger farms have production services that store integrated antimicrobial use data through software systems. Smaller farms have a different production model and are generally less integrated ,with their record keeping system presenting many sources of data (e.g., veterinarian, feed lot, or farm). This lack of standardization presents a challenge when trying to understand how antimicrobials are used across all farms of the same commodity in the US. Without access to a broad range of data, a representative picture of antimicrobial use is difficult to capture.

Clear data access and privacy protection are essential to build and maintain mutual trust among public and private partners.

Establishing clear boundaries to govern data access and privacy are needed to obtain RWD, which are required to build and maintain mutual trust between public and private partners. During the one-on-one discussions and the roundtable discussion, stakeholders expressed concerns about potential public disclosure of information that can be used to identify individual farms or expose confidential business information. To minimize the risk of improper disclosure of personally identifiable or confidential business information, stakeholders must set clear disclosure boundaries of a public-private partnership that will house the data repository. Given that antimicrobial use data may have commercial value, clear guidance of data access, data sharing and data ownership will need to be addressed to build and maintain the mutual trust between all partners.

Providing transparency and confidentiality for the data that are collected is essential to provide a comprehensive picture of antimicrobial use. Ensuring that appropriately aggregated, de-identified data that maintains confidential business information may be used to promote industry trust and participation, research efforts to support animal and public health, and public confidence. Aggregated national data could help meet the needs of regulators and consumers as well as provide benchmark data to help veterinarians work with producers to promote antimicrobial stewardship and cost-effective use.

Draft Principles

Key themes from one-on-one discussions were used to inform the following draft principles to support a public-private partnership and are presented here for discussion.

Purpose and Intended Outcomes

- Monitoring of antimicrobial use in food-producing animals can lead to a better understanding of trends across each species/commodity group, regions and time, and will foster more optimal, antimicrobial stewardship of medically important antimicrobial drugs.
- The One Health approach, which considers all sectors where antimicrobials are used, including human and animal use, is important to understanding if and how antimicrobial use and resistance are related. Antimicrobial stewardship in food-producing animals is intended to help

preserve antimicrobial efficacy for animals and people in our shared environment. Antimicrobial stewardship is not intended to reduce antimicrobial use to zero, but collecting antimicrobial use data and monitoring trends across all commodities is a first step to understanding the complex relationship between antimicrobial use and AMR.

- A well-constructed public-private partnership could generate information on the use of antimicrobials in food-producing animals in relationship to animal health and welfare. The data can be used for reports and analysis that are useful and trusted by the public.
- Sufficient data from a variety of data sources, including producers and veterinarians, can provide a comprehensive picture of antimicrobial use in the context of animal health and welfare.

Scope

- Context, such as the number, size, species of animals, and indication, is essential to understand antimicrobial use in food-producing animals.
- Standardized protocols agreed upon in advance of data collection (including the metrics of antimicrobial use to be collected) is imperative to stakeholder participation and willingness to share data.
- One size does not fit all. Each species requires capture and analysis of different data elements. Data capture and compilation should recognize the varying structure and stages of development for each species sector. Data are not comparable between species.
- Analyses and summary reports of data, and any data disclosure, must protect confidential business information.
- Data contributors and analyzers must prioritize data quality, provenance, and integrity and develop a process by which data is blinded to retain confidentiality. Respecting those who generate and contribute the data, as well as those who curate and analyze the data, yields trust, understanding, and confidence in the results.
- Transparency is essential. Methodologies and analyses, with sufficient context, should be shared broadly, including with veterinarians, producers, public health officials, and the public.
- Embrace continuous learning and improvement. Recognize that agreed-upon methods of capturing and analyzing data may provide an improved picture of antimicrobial use.

Next Steps

Recognizing that we are just beginning to scratch the surface with these conversations and actions, and that this is an incredibly challenging area to generate consistent and nationally representative data, FDA plans to open a docket where they invite the public to comment. In that docket we encourage interested individuals to provide comments on this report, additional proposed ideas, identify possible data holders, etc. that would be helpful in order to develop a framework for a public-private partnership.

Using comments received from that docket, FDA will develop a proposal for collecting antimicrobial use data in food-producing animals and collaborate with the FDA Foundation to solicit additional participation from the roundtable participants (listed below in [Appendix II](#)) in order to further advance this effort.

There will be opportunities for additional roundtable discussions as the technical aspects of the framework for a potential public-private partnership are established.

For additional information please see: [Insert RUF public forum meeting webpage and docket website]

Appendix I: Virtual Roundtable Agenda

Tracking and Monitoring Antimicrobial Use in Food-Producing Animals

Virtual Expert Roundtable

Thursday, March 31

1 – 4 p.m. Eastern Time

Agenda

Meeting Purpose: The Reagan-Udall Foundation for the FDA, at the request of FDA’s Center for Veterinary Medicine (CVM), is convening a roundtable of stakeholders to discuss the feasibility of creating a public-private partnership to build a data repository related to antimicrobial drug use in food-producing animals. The discussion will focus on the potential purpose, benefits, limitations, and challenges to collecting and sharing findings from those data to a variety of interested parties, including government agencies, researchers/academia, consumer advocacy groups, industry, and the public.

1 p.m. Welcome

Speaker: Susan C. Winckler, RPh, Esq, Chief Executive Officer, Reagan-Udall Foundation for the FDA

1:05 p.m. Opening Remarks from U.S. Food and Drug Administration

Speaker: William Flynn, DVM, MS, Deputy Director, Center for Veterinary Medicine, FDA

1:15 p.m. Participant Introductions

Moderator: Susan C. Winckler, RPh, Esq

When called on, please share your name, organizational affiliation, and name one potential benefit or one potential risk of a public-private partnership to collect, analyze, and disseminate aggregated data related to antimicrobial use in food-producing animals. (1-2 minutes each)

1:40 p.m. Case Study 1: Data Reporting in the Poultry Industry

Presenter: Denise L. B. Heard, DVM, MAM, ACPV, U.S. Poultry & Egg Association

1:50 p.m. Case Study 2: Data Sharing in the Dairy Industry

Presenter: Jordan Kraft Lambert, MBA, VAS

2 p.m. Draft Principles for a Public-Private Partnership

Presenter: Amar Bhat, PhD, Reagan-Udall Foundation for the FDA

2:10 p.m. Group Discussion

Moderator: Susan C. Winckler

3:50 p.m. Next Steps

4 p.m. Adjournment

Appendix II: Stakeholder Organizations

The following organizations participated in one-on-one conversations and/or the in-depth roundtable discussion. The FDA Foundation would like to thank these organizations for their participation.

Research/Academia and Consumer Groups

- Food Animal Concerns Trust
- Food Armor Foundation
- Foundation for Food and Agriculture Research
- George Washington University Antibiotic Resistance Action Center
- International Consortium for Antimicrobial Stewardship in Agriculture
- Iowa State University
- Kansas State University College of Veterinary Medicine
- National Institute of Antimicrobial Resistance Research & Education
- Natural Resource Defense Council
- The Pew Charitable Trusts
- University of Minnesota Department of Veterinary and Biomedical Sciences
- University of Minnesota Department of Veterinary Population Medicine

Veterinarians and Clinical Supporting Companies

- American Veterinary Medical Association
- Dairy Veterinarian Group
- Pipestone Veterinary Services
- VAS (Valley Ag Software)
- Zoetis Animal Health

Trade Organizations for Producers

- Animal Health International
- Beef Alliance
- National Cattlemen's Beef Association
- National Milk Producers Federation
- National Pork Board
- National Pork Producers Council
- National Turkey Federation
- U.S. Poultry and Egg Association

Animal Drug Manufacturers

- Generic Animal Drug Alliance

Government Agencies

- Maryland Department of Agriculture
- U.S. Centers for Disease Control and Prevention
- U.S. Department of Agriculture
- U.S. Food and Drug Administration Center for Veterinary Medicine



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The following key themes emerged from the discussion:

- Antimicrobial sales and distribution data and antimicrobial use data are not the same.
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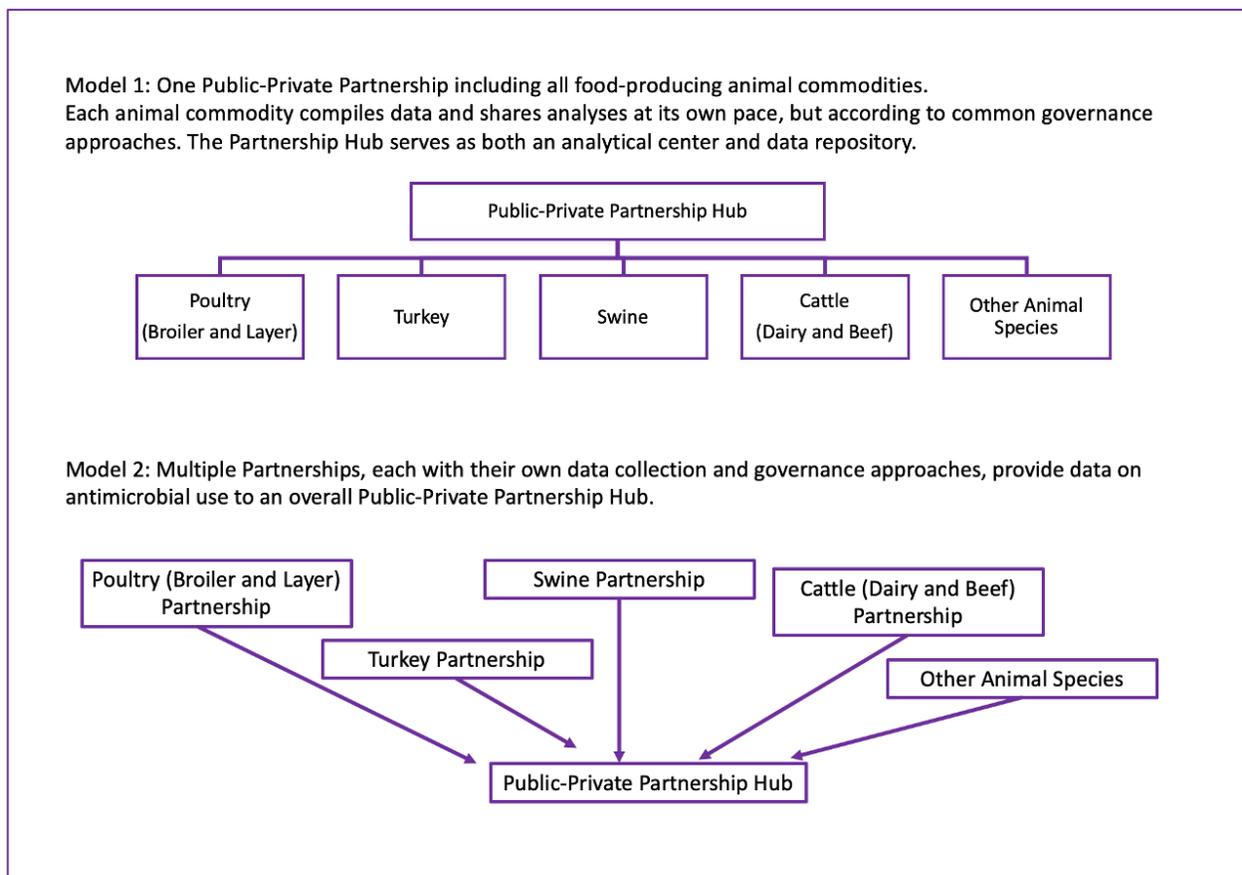


Figure 1: Sample public-private partnership structures.

Such a partnership could generate data and analyses for a variety of stakeholders, including other federal agencies and policymakers, researchers, veterinarians, academia, consumer advocacy groups, industry, and the public. To develop a robust and sustainable RWD system, recognizing that the goal is not to reduce AMU to zero use (which would result in animals untreated for addressable conditions), it is essential to engage stakeholders who are involved in all aspects of the food-producing animal supply chain, including feed manufacturers, drug sponsors, producers, veterinarians, and others who generate and own the relevant data.

Stakeholder Meetings and Virtual Roundtable

To understand the feasibility of setting up a public-private partnership to collect antimicrobial use in food-producing species, the FDA Foundation conducted several one-on-one and small group conversations with key stakeholders. Discussions focused on the potential purpose, benefits, limitations, and challenges to collecting and sharing trends from those data. Stakeholders provided insights into the landscape of efforts to collect and analyze antimicrobial use data as well as the benefits and challenges for those efforts. The conversations led to key themes that informed the initial version of the draft objective and principles to support establishing a potential public-private partnership to support the tracking and monitoring of antimicrobial use in food-producing animals.

The FDA Foundation met with 30 stakeholders with expertise in the use of antimicrobials in the food-producing animal supply chain. These stakeholders, identified with input from FDA, provided insights into animal movements within the different animal commodities through animal production; how antimicrobial use data is collected and maintained; and the feasibility of a potential of a public-private partnership. Table 1 summarizes the categories of stakeholders who participated in small group conversations and the roundtable discussions.[‡]

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Animal Drug Manufacturer	1

Virtual Roundtable

In late March 2022, the FDA Foundation held an in-depth virtual roundtable to discuss the feasibility of creating a public-private partnership to support the tracking and monitoring of antimicrobial use in food-producing animals of antimicrobial drug use in food-producing animals.[§] Participants included organizational and individual stakeholders who are responsible for the generation, collection, storage, and maintenance of primary on-farm data related to antimicrobial use in food-producing animals. The discussion focused on the potential purpose, benefits, limitations, and challenges to collecting and sharing findings from those data to a variety of interested parties, including government entities, researchers/academia, consumer advocacy groups, industry, and the public. Participants discussed the objective and draft principles for a public-private partnership.

[‡] A full list of stakeholder organization names is included in [Appendix II](#).

[§] The agenda for the roundtable meeting is included in [Appendix I](#).

Objective of a Public-Private Partnership

While discussing the objective of the partnership, participants noted that a data repository could be useful and improve efficiency by consolidating existing efforts to collect antimicrobial use data. A data repository facilitated through a public-private partnership could provide additional assurances of data security and integrity. The partnership could present an opportunity for collaboration among different commodities, as well establish standardized methods for data collection across commodities. Summary reports could provide producers with benchmark data to understand antimicrobial use in comparison to national trends and make data-driven decisions to support improved antimicrobial stewardship. Overall, a potential partnership could promote antimicrobial stewardship efforts benefiting animal welfare and would support a One Health approach to understanding antimicrobial use and AMR.

After a robust discussion, the overall objective of a potential partnership is summarized as:

Gathering antimicrobial use data in food-producing animals to foster antimicrobial stewardship and animal health and welfare.

Key Themes

In addition to consensus about the goals of a public-private partnership, key themes emerged from the conversations and roundtable discussion. They are summarized in the sections below.

Antimicrobial sales and distribution data and antimicrobial use data are not the same.

In the absence of accurate antimicrobial use data, sales and distribution data are often incorrectly used as a proxy for use data, even though sales do not represent actual use of the products. Sales and distribution data represent the volume of antimicrobials sold into distribution, and thus represent the maximum amount of product that could have been administered to animals. (For example, veterinarians and animal producers may purchase drugs, but may not actually administer them to animals, or they may be administered in later years.) The data do not represent the amount of antimicrobials that were ultimately administered to any animals, and for what indication (e.g., to treat an active infection or risk of infection). Without adequate collection of antimicrobial use data, including context for use such as disease indication, an accurate picture of use cannot be generated, and thus is not available to optimize antimicrobial stewardship or evaluate associations between antimicrobial use and AMR.

Context, such as the number, size, species of animals, and indication, is essential to understand antimicrobial use in food-producing animals.

Another of the challenges mentioned throughout stakeholder conversations is the risk of data being shared broadly without providing sufficient context. Providing context with aggregated use data supports accurate interpretation and reduces the potential for misuse or misrepresentation of data. Stakeholders highlighted that contextual information, such as how and when data are collected, can provide a clearer understanding of drivers of antimicrobial stewardship. Without appropriate context, the public may associate “high” use of antimicrobials with “bad”, and similarly associate “low” use of antimicrobials with “good.” Such overly simplistic interpretations of antimicrobial use data do not account for the relative potency of different antimicrobials or external factors that impact use, such as baseline animal disease or external factors impacting on-farm use. For example, an outbreak of a disease among the population of a specific species might necessitate a substantial increase in the amount of a specific antimicrobials used in that time period. Furthermore, the duration of therapeutic antimicrobials often differs by species and drugs. The indication for antimicrobial use is an additional

data point required to provide additional context. Another important variable is the demographic data, for example, animal population size, farm, lot, production category, etc., since these factors vary by species. Additional research is needed to understand which variables are essential for a potential RWD repository.

Collecting standardized data across species and routes of administration will be challenging. Heterogeneity of animal production classes and farming systems exist both among and within food-producing animal species. These differences impact whether and how antimicrobial use data are collected. Many farms, such as smaller-scale farms, may rely on paper records regarding antimicrobial use and those paper records may not move with the animals. Paper records also pose challenges for electronic reporting and interoperability. Data elements such as weights, dosage of antimicrobial given, name of antimicrobial given, and route of administration may not be measured or recorded consistently across farms of the same species or across the different species. For example, farmers might have different methods for estimating animals' weights or might record estimated weights in different unit (e.g., pounds vs. kilograms). Additionally, if an electronic health record system is used, then there could be challenges navigating different types of health record platforms. The issues of lack of data standardization, record system interoperability, and inconsistent or missing data present significant challenges for setting quality metrics or benchmarking certain measures for comparison.

Additionally, stakeholders stated that there may be a need for encouragement for collecting standardized data. Incentivizing through benchmarking methods or monetary methods may be required. This could provide stakeholders with a reward for collecting data needed to foster antimicrobial stewardship.

Many stakeholders also emphasized the importance of providing transparency of methodologies for data collection and standardization. Establishing methodologies for how the data are collected, reported, transformed, and analyzed prior to collecting such data is also very important factor. However, when establishing standardized methodologies, one must recognize that not all commodities are the same and this is one of the key challenges identified.

Each food-producing species or food commodity requires unique considerations and species-specific data should not be directly compared to other species.

During the roundtable discussion, comments underscored that each commodity requires the capture and analysis of different data elements; therefore, each commodity needs to be viewed with a different lens.

The movement of animals throughout their productive life is different for each commodity. The poultry sector, including chickens and turkeys, for example, is more vertically integrated than other sectors. In most cases, a broiler chicken will stay on one farm from birth until slaughter, while layer chicken, turkey, swine, and cattle will travel across different farms. For broiler chickens, layer chickens, turkey, and swine, there are commonly production companies that provide veterinarian services to farms. Therefore, most antimicrobials will be prescribed and administered through the production companies. This provides an opportunity to capture antimicrobial use data from the companies. For cattle, production companies are not as involved in providing veterinary services. Dairy and beef cattle more commonly have independent veterinarians that provide veterinary services. These services can be provided at any stage during the animal's life which present many opportunities to capture AMU data.

Even though data are collected at the farm level, those data may not move as the animal cycles through different farms. Different commodities generate and collect data in different ways that may require different approaches and methodologies for capturing antimicrobial use data. Therefore, differences between animal commodities needs to be considered when establishing an effective public-private partnership or partnership(s) and data repository.

Additionally, different production models exist between or within commodities. Many larger farms have production services that store integrated antimicrobial use data through software systems. Smaller farms have a different production model and are generally less integrated ,with their record keeping system presenting many sources of data (e.g., veterinarian, feed lot, or farm). This lack of standardization presents a challenge when trying to understand how antimicrobials are used across all farms of the same commodity in the US. Without access to a broad range of data, a representative picture of antimicrobial use is difficult to capture.

Clear data access and privacy protection are essential to build and maintain mutual trust among public and private partners.

Establishing clear boundaries to govern data access and privacy are needed to obtain RWD, which are required to build and maintain mutual trust between public and private partners. During the one-on-one discussions and the roundtable discussion, stakeholders expressed concerns about potential public disclosure of information that can be used to identify individual farms or expose confidential business information. To minimize the risk of improper disclosure of personally identifiable or confidential business information, stakeholders must set clear disclosure boundaries of a public-private partnership that will house the data repository. Given that antimicrobial use data may have commercial value, clear guidance of data access, data sharing and data ownership will need to be addressed to build and maintain the mutual trust between all partners.

Providing transparency and confidentiality for the data that are collected is essential to provide a comprehensive picture of antimicrobial use. Ensuring that appropriately aggregated, de-identified data that maintains confidential business information may be used to promote industry trust and participation, research efforts to support animal and public health, and public confidence. Aggregated national data could help meet the needs of regulators and consumers as well as provide benchmark data to help veterinarians work with producers to promote antimicrobial stewardship and cost-effective use.

Draft Principles

Key themes from one-on-one discussions were used to inform the following draft principles to support a public-private partnership and are presented here for discussion.

Purpose and Intended Outcomes

- Monitoring of antimicrobial use in food-producing animals can lead to a better understanding of trends across each species/commodity group, regions and time, and will foster more optimal, antimicrobial stewardship of medically important antimicrobial drugs.
- The One Health approach, which considers all sectors where antimicrobials are used, including human and animal use, is important to understanding if and how antimicrobial use and resistance are related. Antimicrobial stewardship in food-producing animals is intended to help

preserve antimicrobial efficacy for animals and people in our shared environment. Antimicrobial stewardship is not intended to reduce antimicrobial use to zero, but collecting antimicrobial use data and monitoring trends across all commodities is a first step to understanding the complex relationship between antimicrobial use and AMR.

- A well-constructed public-private partnership could generate information on the use of antimicrobials in food-producing animals in relationship to animal health and welfare. The data can be used for reports and analysis that are useful and trusted by the public.
- Sufficient data from a variety of data sources, including producers and veterinarians, can provide a comprehensive picture of antimicrobial use in the context of animal health and welfare.

Scope

- Context, such as the number, size, species of animals, and indication, is essential to understand antimicrobial use in food-producing animals.
- Standardized protocols agreed upon in advance of data collection (including the metrics of antimicrobial use to be collected) is imperative to stakeholder participation and willingness to share data.
- One size does not fit all. Each species requires capture and analysis of different data elements. Data capture and compilation should recognize the varying structure and stages of development for each species sector. Data are not comparable between species.
- Analyses and summary reports of data, and any data disclosure, must protect confidential business information.
- Data contributors and analyzers must prioritize data quality, provenance, and integrity and develop a process by which data is blinded to retain confidentiality. Respecting those who generate and contribute the data, as well as those who curate and analyze the data, yields trust, understanding, and confidence in the results.
- Transparency is essential. Methodologies and analyses, with sufficient context, should be shared broadly, including with veterinarians, producers, public health officials, and the public.
- Embrace continuous learning and improvement. Recognize that agreed-upon methods of capturing and analyzing data may provide an improved picture of antimicrobial use.

Next Steps

Recognizing that we are just beginning to scratch the surface with these conversations and actions, and that this is an incredibly challenging area to generate consistent and nationally representative data, FDA plans to open a docket where they invite the public to comment. In that docket we encourage interested individuals to provide comments on this report, additional proposed ideas, identify possible data holders, etc. that would be helpful in order to develop a framework for a public-private partnership.

Using comments received from that docket, FDA will develop a proposal for collecting antimicrobial use data in food-producing animals and collaborate with the FDA Foundation to solicit additional participation from the roundtable participants (listed below in [Appendix II](#)) in order to further advance this effort.

There will be opportunities for additional roundtable discussions as the technical aspects of the framework for a potential public-private partnership are established.

For additional information please see: [Insert RUF public forum meeting webpage and docket website]

Tracking and Monitoring Antimicrobial Use in Food-Producing Animals

Virtual Expert Roundtable

Thursday, March 31

1 – 4 p.m. Eastern Time

Agenda

Meeting Purpose: The Reagan-Udall Foundation for the FDA, at the request of FDA’s Center for Veterinary Medicine (CVM), is convening a roundtable of stakeholders to discuss the feasibility of creating a public-private partnership to build a data repository related to antimicrobial drug use in food-producing animals. The discussion will focus on the potential purpose, benefits, limitations, and challenges to collecting and sharing findings from those data to a variety of interested parties, including government agencies, researchers/academia, consumer advocacy groups, industry, and the public.

1 p.m. Welcome

Speaker: Susan C. Winckler, RPh, Esq, Chief Executive Officer, Reagan-Udall Foundation for the FDA

1:05 p.m. Opening Remarks from U.S. Food and Drug Administration

Speaker: William Flynn, DVM, MS, Deputy Director, Center for Veterinary Medicine, FDA

1:15 p.m. Participant Introductions

Moderator: Susan C. Winckler, RPh, Esq

When called on, please share your name, organizational affiliation, and name one potential benefit or one potential risk of a public-private partnership to collect, analyze, and disseminate aggregated data related to antimicrobial use in food-producing animals. (1-2 minutes each)

1:40 p.m. Case Study 1: Data Reporting in the Poultry Industry

Presenter: Denise L. B. Heard, DVM, MAM, ACPV, U.S. Poultry & Egg Association

1:50 p.m. Case Study 2: Data Sharing in the Dairy Industry

Presenter: Jordan Kraft Lambert, MBA, VAS

2 p.m. Draft Principles for a Public-Private Partnership

Presenter: Amar Bhat, PhD, Reagan-Udall Foundation for the FDA

2:10 p.m. Group Discussion

Moderator: Susan C. Winckler

3:50 p.m. Next Steps

4 p.m. Adjournment

Appendix II: Stakeholder Organizations

The following organizations participated in one-on-one conversations and/or the in-depth roundtable discussion. The FDA Foundation would like to thank these organizations for their participation.

Research/Academia and Consumer Groups

- Food Animal Concerns Trust
- Food Armor Foundation
- Foundation for Food and Agriculture Research
- George Washington University Antibiotic Resistance Action Center
- International Consortium for Antimicrobial Stewardship in Agriculture
- Iowa State University
- Kansas State University College of Veterinary Medicine
- National Institute of Antimicrobial Resistance Research & Education
- Natural Resource Defense Council
- The Pew Charitable Trusts
- University of Minnesota Department of Veterinary and Biomedical Sciences
- University of Minnesota Department of Veterinary Population Medicine

Veterinarians and Clinical Supporting Companies

- American Veterinary Medical Association
- Dairy Veterinarian Group
- Pipestone Veterinary Services
- VAS (Valley Ag Software)

Trade Organizations for Producers

- Beef Alliance
- National Cattlemen's Beef Association
- National Milk Producers Federation
- National Pork Board
- National Pork Producers Council
- National Turkey Federation
- U.S. Poultry and Egg Association

Animal Drug Manufacturers

- Animal Health Institute
- Generic Animal Drug Alliance
- Zoetis Animal Health

Government Agencies

- Maryland Department of Agriculture
- U.S. Centers for Disease Control and Prevention
- U.S. Department of Agriculture
- U.S. Food and Drug Administration Center for Veterinary Medicine