



SUMMARY REPORT

Establishing a Draft Framework for a Public-Private Partnership to Support the Tracking of Antimicrobial Use in Food-Producing Animals

AUGUST 2023

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of \$114,913 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

CONTENTS

- Executive Summary** 3
- Background** 4
- Working Group Meetings** 6
- Potential Framework for Establishing a Public Private Partnership to Collect Data about the Use of Antimicrobial Drugs in Animals** 7
 - Objectives of the Public-Private Partnership 7
 - Public-Private Partnership Framework 8
 - Organizational Structure 8
 - Interaction Between Third-Party Data Repository Coordinator (DRC) and External Data Partners (EDPs) 10
 - Financial Support 11
 - Phased Addition of the DRC and EDPs 12
 - AMU Data Collection Infrastructure 12
 - Data Sourcing and Data Repository 12
 - Data Ownership, Confidentiality and Security 13
 - Data Quality and Verification Processes 14
 - Data Elements 14
 - Reporting Structure 18
- Appendix I** 19
- Appendix II** 20
- Appendix III** 21

EXECUTIVE SUMMARY

Antimicrobial resistance (AMR) is recognized as a growing global threat requiring action in new product research and development and greater stewardship of antimicrobial use (AMU) in human and animal health. Currently, limited AMU data are available in food producing animals, which makes it challenging to improve antimicrobial stewardship and to better understand the relationship between AMR and AMU. As part of ongoing activity to explore AMU data collection under a PPP framework, the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) engaged the Reagan-Udall Foundation for the FDA (FDA Foundation) in two phases. Phase 1 focused on facilitating conversations with relevant stakeholders to assess the feasibility of creating a public-private partnership (PPP) to develop an antimicrobial drug use data repository to foster antimicrobial stewardship in food-producing animals. Phase 2 focused on outlining a potential framework to set up a PPP.

In phase 2, from November 2022 to March 2023, the FDA Foundation convened a working group consisting of stakeholder representatives to discuss various PPP topics such as data standardization, organizational structure (i.e., governance of the PPP), finance, public reporting, and data analysis. Through these meetings, the FDA Foundation sought to understand better the interests and concerns of the various stakeholders in relation to the potential framework. The working group consisted of professional associations representing food-producing animal sectors and experts that work directly with AMU data. This initial framework is shared in this report with “discussion highlights” from the working group members.

FDA, in collaboration with the FDA Foundation, created this potential framework as the initial basis for discussion with stakeholders. The draft framework was developed for discussion purposes only. While working group members were consulted, these organizations did not endorse the final report, nor is their endorsement implied. Nothing in the framework or this report should be considered final as the concepts will be further refined, informed, and expanded by these and future discussions.

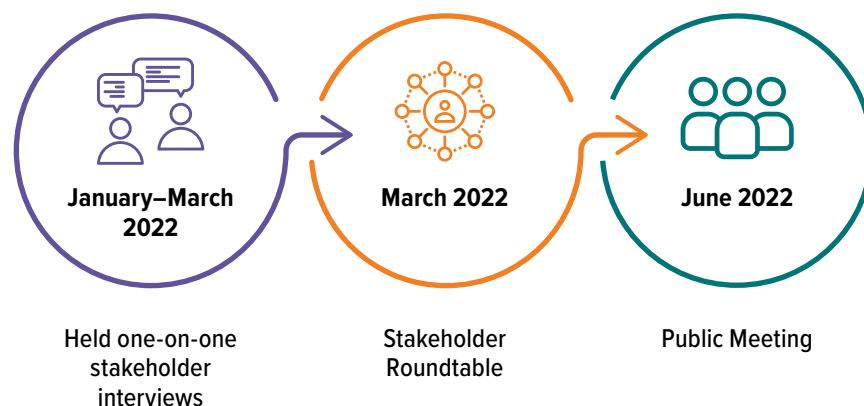
BACKGROUND

Antimicrobial resistance (AMR) is recognized as a growing global threat requiring action in new product research and development and greater stewardship of antimicrobial use in human and animal health. AMR can be viewed through the One Health¹ approach, which recognizes that the health of humans, animals, and the environment are interconnected. Currently there is no national data repository or infrastructure developed for the purposes of collecting nationally representative antimicrobial use data in animals, which makes it difficult to characterize the relationship between AMU and AMR in food-producing animals.

As part of ongoing activity² to better understand the relationship between AMU and AMR, 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 (PPP) to develop an AMU data repository to foster antimicrobial stewardship in food-producing animals. While this CVM-funded activity was primarily focused on certain food-producing animals, the FDA is also interested in better understanding AMU trends in other species, such as companion animals and minor species.

For the purpose of this effort, the definition of “antimicrobial use” is the amount of antimicrobial prescribing, authorizing, administering, and delivering for administration in a defined animal species or population.

In late 2021, the FDA Foundation launched phase 1 of this work and facilitated discussion with 30 stakeholders on the feasibility of setting up a PPP to track and monitor AMU. Stakeholders included food-producing animal trade associations, researchers, academics, consumer advocacy groups, and government agencies. These meetings were conducted through one-on-one conversations, a roundtable discussion, and a public meeting. Through the March 2022 roundtable discussion, stakeholders developed the following objective of a PPP:



1 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.

2 See Appendix III for more information on current FDA CVM activities in the area of antimicrobial use.



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

Common themes emerged from the roundtable and public meeting discussion:

- Antimicrobial sales and distribution data and antimicrobial use data are not the same.
- Context, such as the animal number, size, and species, and indication for product use, 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-specific 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 key themes from the roundtable led to the development of principles that informed the work for phase 2. These principles can be found in Appendix I. The full report detailing the discussion from phase 1 as well as the video recording of the June 2022 public meeting can be accessed on the FDA Foundation’s website by clicking [here](#).

WORKING GROUP MEETINGS

In phase 2, the FDA Foundation built on phase 1 work by facilitating meetings with stakeholders who work directly with AMU data to discuss concepts that are integral to developing a successful PPP. Through a series of working group meetings held from November 2022 to March 2023, participants discussed topics such as organizational structure of the PPP, AMU data standardization, data metrics, data reporting, and finance. FDA, in collaboration with the FDA Foundation, drafted an initial framework that formed the basis of discussion with working group members. These discussions resulted in a better understanding of the needed characteristics of a PPP to capture and house AMU data.

While working group members were consulted, these organizations did not endorse the final report, nor is their endorsement implied. Nothing in the framework or this report should be considered final as the concepts will be further refined, informed, and expanded by these and future discussions.

Figure 1 shows the timeline of working group meetings. The list of working group participants can be found in Appendix II.

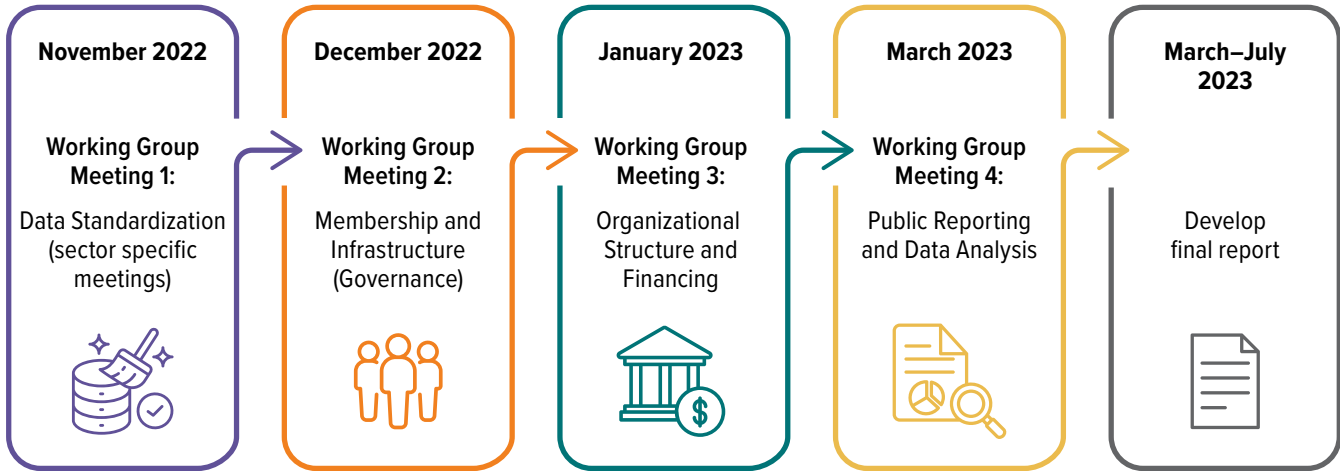


Figure 1: Timeline of Working Group meetings.

POTENTIAL FRAMEWORK

for Establishing a Public Private Partnership to Collect Data about the Use of Antimicrobial Drugs in Animals

OBJECTIVES OF THE PUBLIC-PRIVATE PARTNERSHIP



DISCUSSION HIGHLIGHTS

During the discussion, working group participants emphasized the need for a partnership that collects representative, accurate, aggregate, and de-identified data. Additionally, they emphasized that there should be controlled access to data, especially raw data which should stay with the data partners.

Regarding minor species and companion animals, even though working group participants stated that it will be challenging to include, companion animals and other minor species are an important to consider within a one health context. Working group participants suggested to keep the initial focus on food-producing animals and include companion animals and minor species at a later stage.

The goals are to establish a public-private partnership framework (PPP) and develop a long-term strategy for implementing a functional and efficient infrastructure for collecting AMU data in animals from diverse veterinary and animal production sectors within the United States. Specific key objectives of a PPP, once established, include:

- Collecting high quality, representative, accurate, aggregated, and de-identified AMU data to monitor trends across diverse veterinary sectors, including major food-producing animals³, companion animal (e.g., dogs, cats, and horses), and minor species.⁴
- Collating and publishing aggregated national AMU data so that it is available to help inform the development of stewardship programs and encourage responsible antimicrobial use across diverse veterinary animal production sectors.
- Providing additional context relevant to regulatory and policy decisions by FDA and other state and federal partners.
- Providing different levels of controlled access to appropriately de-identified and aggregated AMU summary data and methodologies through effective reporting structures.

³ "Food-producing animals" are animals from which food (e.g., meat, milk, eggs) is derived.

⁴ "Minor species" are all animals other than humans that are not one of the seven major species (cattle, horses, swine, chickens, turkeys, dogs, and cats). They include animals such as zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are minor species. These include sheep, goats, catfish, game birds, and honeybees among others.

PUBLIC-PRIVATE PARTNERSHIP FRAMEWORK

Organizational Structure



DISCUSSION HIGHLIGHTS

Throughout the discussions regarding organizational structure of the PPP (also referred to in discussions as “governance”), the working group participants emphasized that any and all entities involved in the partnership must develop a relationship among public and private sectors based on trust. Additionally, the different entities involved in the organizational structure must collaborate effectively to have a successful partnership. The different entities are FDA’s CVM, Steering Committee members, a third-party Data Repository Coordinator (DRC), and External Data Partners who contribute data. Collaboration and trust are emphasized throughout the proposed organizational structure of the partnership.

A successful PPP framework will require collaboration and trust between public and private sectors to support AMU data collection. To support AMU data infrastructure development, a proposed organizational structure includes multiple interrelated and interacting entities, including FDA CVM, a third-party Data Repository Coordinator (DRC), a Steering Committee, and External Data Partners (EDPs).

Specific activities and roles for each entity are outlined below:

FDA CVM – FDA would facilitate development of a PPP and long-term strategy for implementing a functional and efficient infrastructure to collect data about the use of antimicrobial drugs in animals.



DISCUSSION HIGHLIGHTS

FDA CVM communicated that it will be the primary funding source for initiating the DRC and EDPs, which would be funded through a competitive grants process. Additionally, a representative from FDA CVM would sit on the Steering Committee and contribute scientific and technical expertise.

Specific activities and roles of the FDA pertaining to the PPP would include:

- Awarding funding to a DRC and EDPs to support a PPP through a competitive grant process, such as a cooperative agreement.⁵
- Collaborating with the DRC to establish effective administrative structures and processes.
- Providing scientific and technical expertise to the PPP on behalf of the Agency, as needed, through participation on the Steering Committee (described below).

Third Party Data Repository Coordinator⁶ — The DRC would develop and establish a database repository to that will receive and securely store aggregated, de-identified, and standardized AMU data, consistent with the oversight and direction of the Steering Committee. The DRC may be an institution with 501(c)(3) status with the ability to pool funds from both private and public entities to support the PPP relationships long-term.

⁵ FDA funding is subject to funding availability and program needs and is expected to be a portion of the funding required to support the work of the DRC and EDPs agreed under the PPP.

⁶ In discussions with stakeholders, the DRC was also commonly referred to as Third-Party Convener (TPC), although the terminology for this entity was later changed.



DISCUSSION HIGHLIGHTS

Regarding the selection process of a DRC, the concept of trust was repeatedly raised by participants in working group discussions. Trust between the DRC and EDPs will be critical when collaborating on the collection and analysis of AMU data. Mutual trust is essential to provide data providers with confidence that their data will be securely held and analyzed in the correct context.

The main role of the DRC will be to build administrative and database infrastructure to support long-term AMU data collection, in collaboration with the Steering Committee. A DRC will be the primary body that will facilitate data aggregation and analysis across the different sectors. The purpose of this aggregation and analysis will be to disseminate annual reports.

The agreed upon specific activities and roles of the DRC on behalf of the PPP would include:

- Establish (with FDA input) key organizational and reporting structures to support the PPP.
- Build administrative and database infrastructure to support long-term AMU data collection.
- Receive de-identified AMU data and metadata from EDPs.
- Collaborate with EDPs and Steering Committee to facilitate data aggregation and analysis across sectors for the purpose of preparing annual reports.
- Provide training or technical expertise to EDPs, either directly or through a consultant.

External Data Partners (EDPs) – EDPs would be trusted partners of the sector from which AMU data are collected. The EDPs may be consultant(s) from industry trade organizations for producers, individual producers or farms, veterinary practices or corporations, veterinarians or clinical support companies, university consultants, and other veterinary organizations or firms contracted by such organizations. Subject to the availability of funds, the collection of data by the EDPs would likely be supported by a combination of FDA and private sector sources.



DISCUSSION HIGHLIGHTS

Throughout the discussion, all participants agreed that any involvement in the PPP by the EDPs should be on a voluntary basis. The voluntary aspect limits the concern that data partners will be forced or penalized for not participating in the partnership.

The individual(s) or organization(s) serving as EDPs for a particular food-producing animal sector must be trusted by the sector constituents and data holders. Because they would understand the “ins and outs” of the sector, an EDP would be in a position to contribute to the trust among the producers and organizations that contribute data. In regard to the composition of the EDP, there was consensus that partners could be consultant(s) from industry trade organizations for producers, individual producers or farms, veterinary practices or corporations, veterinarians or clinical support companies, university consultants, and other veterinary organizations or institutions.

Regarding the collection of data, working group participants confirmed the importance of the EDP in retaining ownership of the raw data and controlling access through data use agreements. This allows the EDPs to collect data with confidence that any sharing of data with external parties such as the PPP will be under controlled terms and conditions.

Specific activities and roles of the EDPs would include:

- Negotiate data use sharing agreements within the PPP, including with the data providers/producers.
- Contribute de-identified AMU data and metadata to the DRC operating under terms of any necessary or established data sharing agreements.
- Maintain controlled access over any raw data and ensure data providers retain ownership of raw data.
- Participate in data verification and quality control activities.
- Provide feedback about PPP organizational structures to the Steering Committee, and vice versa.

Steering Committee – The Steering Committee would establish and update the priorities of the PPP over time to ensure that the short- and long-term objectives for AMU data collection are being met. Membership on the Steering Committee would be limited to representatives of organizations which contribute data and resources to the PPP, including leaders from the EDPs, DRC, and FDA.



DISCUSSION HIGHLIGHTS

Working group participants supported an approach where Steering Committee membership would include only representatives of entities that contribute AMU data and/or funding.

Specific activities and roles of the Steering Committee include:

- Convene regularly to discuss program progress, future directions, and program enhancements over time.
- Provide program direction and guidance to the DRC and EDPs.
- Provide leadership to support pursuit of additional funding opportunities.
- Review and approve data analytic work streams, including dissemination plans.

Interaction Between Third-Party Data Repository Coordinator (DRC) and External Data Partners (EDPs)



DISCUSSION HIGHLIGHTS

The collaboration between the DRC and EDPs is important in ensuring that the PPP is productive. This graphic was added to the Framework to help illustrate the interaction between the DRC and EDPs.

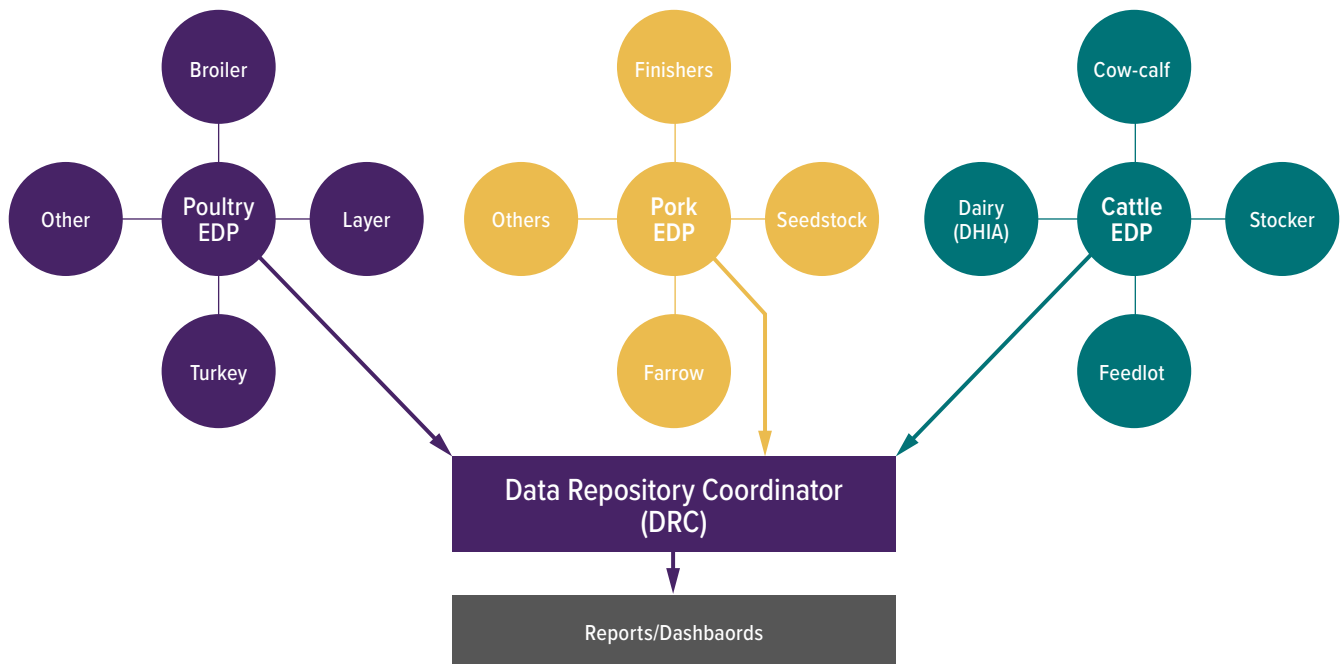


Figure 3: Interaction between EDPs and the DRC.

EDPs will lead collection and, in some cases, analysis of their sector’s data. Phased implementation of distinct veterinary sectors is expected. The flow of data could be:

1. Individual producers or data holders collect and share their data with their designated EDP under the terms of any specific data use agreements.
2. EDP de-identifies data so no specific producers or farms are identifiable and then transfers summary data to the DRC under terms of the DRC.
3. DRC receives data from EDPs into a secure data repository, performs any additional analyses, and finally publishes reports under guidance of the Steering Committee.

Financial Support



DISCUSSION HIGHLIGHTS

The financial cost of a PPP will depend on factors such as which entity is selected as DRC. With both models (described below), participants expressed general concerns about a steady revenue stream to keep the PPP running once the initial set up is complete.

The PPP will encourage collection of data about the use of antimicrobials in animals by fostering cooperation, trust, and collaboration among public and private organizations, data partners and individual data providers. Detailed or individual level AMU data could represent sensitive business information and potential financial value for companies and individuals. While collection of such data will likely have some intrinsic value to EDPs and data holders, the PPP should leverage mechanisms to offset or incentivize the time, effort, and cost to animal producers, veterinarians, and practices associated with voluntary production of raw data to the EDPs.

One of two notional financial structures could be used to support the operations of a DRC to support the mission of the PPP. Both examples assume the need for one full-time director, one data science specialist, and one agricultural/veterinary specialist plus basic infrastructure and equipment. Savings could be achieved potentially by either combining some positions or making some positions part-time.

1. **DRC as an independent organization:** The structure will likely require higher start-up costs due to need for basic infrastructure such as rent, information technology, and administrative/human resource assistance. The actual cost would depend on several factors, such as location.
2. **DRC activity as a subcomponent of another organization:** This structure will likely have smaller start-up costs, as the PPP should be able to leverage the infrastructure provided by the larger organization. The actual cost would depend on several factors such as indirect cost rate of the host organization.

Additional resources and infrastructure (such as information technology and analytical expertise, as well as financial resources, may be necessary to support the EDPs. As such, EDPs representing different animal sectors will have expenses, which may be supported by a combination of private and public (FDA) funding. This does not include additional money that individual stakeholders may choose to invest or expansions into other species groups.

Phased Addition of the DRC and EDPs



DISCUSSION HIGHLIGHTS

The sectors with an existing infrastructure for AMU data collection expressed concern regarding a compelled transition to a new, or revised, data model. The participants agreed, however, that the PPP should be able to work with the existing data collection infrastructures for each sector without requiring significant modifications.

Given the wide range of business and practice models across veterinary and animal production sectors, some sectors will be more prepared in the beginning to contribute AMU data collection activities compared to others. This may mean that a staged approach will be required for the different sectors.

AMU DATA COLLECTION INFRASTRUCTURE

Data Sourcing and Data Repository

The DRC would be responsible for building the PPP's AMU data collection tools, pipelines, and databases required to source, standardize, and securely store aggregated, de-identified AMU data. These tools may take time to develop and would likely be developed in collaboration with the EDPs.

Specific goals for AMU data collection system include to:

- Design and build advanced data collection tools and storage system(s) that reduce costly and labor-intensive manual record review or extraction, thereby reducing burden to data providers.
- Provide structures and tools to allow data system interoperability, promoting flexible use of diverse data sources.

- Maintain controlled access of data to protect confidentiality of veterinary medical records and anonymity of the data. This is to help assure that differences between animal production systems or veterinary practices are not disclosed such that competitiveness or ability to market animals, services or products impacted.
- Leverage advanced terminology standardization methodologies, such as natural language processing (NLP), to standardize data across a variety of data sourced from diverse veterinary and animal production sectors for the purposes of trend evaluation of antimicrobials used (but not to provide cross-species comparisons).
- Support maturation of advanced analytics, including machine learning, to improve AMU data collection and develop best practices for using them.
- Assure private data contributors (i.e., producers) would retain ownership of the raw data, including control over its access.

Data Ownership, Confidentiality and Security



DISCUSSION HIGHLIGHTS

Stakeholders emphasized the importance of privacy and security protections for the data, and for contributors of those data. Additionally, working group members emphasized that it is important for the data to be owned by the data partners and that any data-sharing be done in a de-identified manner. Finally, access to data should be managed in a manner by which data and data providers are protected.

As noted above, implementation of a successful PPP framework to support AMU data collection requires assurances of data privacy and security protections for all data contributors. All data collection must ensure the confidentiality and anonymity of data contributors (i.e., producers) who would retain ownership of their raw data and retain control over its access.

Different levels of AMU data access will be outlined in the data use and sharing agreements. Various controlled access levels would need to be specified for each stage of data collection, verification, analysis, and reporting.

- **Primary level access** would be restricted to owners of the raw data, and this level of access would remain restricted to EDP staff, and/or subcontractors (such as university institutions collaborating with those data partners or contributors).
- **Secondary level access** would include access to EDP data managers and/or DRC technicians with the intent of providing oversight for the secure data transmission/encryption processes, data verification, and quality control (“cleaning” procedures). This level of access would not include raw data for any party other than the EDPs to protect confidential business information.
- **Tertiary level access** would include access to aggregated and de-identified summary data, analytical files, and advanced analytical tools that have undergone data encryption, verification, and quality control procedures. This level of access would be limited to authorized data scientists and statisticians employed by the DRC, Steering Committee members, and FDA staff.
 - o If third party researchers request to access the aggregated/de-identified datasets for the purposes of independent analyses, this may be authorized by the Steering Committee.
 - o Any individual with this form of access would be required to sign non-disclosure agreements.
- General Public level access would include internet postings by the DRC of AMU metric summary data, such as summary reports and peer-reviewed scientific publications, and basic interactive tables/charts (e.g., dashboard or other data display tools), and any other information the Steering Committee authorizes the DRC to post.

Data Quality and Verification Processes

Data quality review and verification are essential to maintaining the integrity of the national AMU dataset. The data quality review process would be a joint effort between certain staff of DRC and the EDPs and should be specified in data use agreements. The DRC would be responsible for developing detailed guidelines and standard operating procedures for EDPs to use when characterizing their own data and metadata for the purposes of sourcing the data into the data repository.

When the data are received, the DRC would be responsible for performing additional quality assurance checks and reporting to the EDP any unresolved issues. Upon completion of error correction and final quality assurances, the dataset would be validated and approved by the DRC. Once approved, the data would be available for tertiary level access. The process for data quality review and verification would be frequently re-evaluated and updated.

Data Elements

Ideally, for AMU data to have the most relevance for inference-making, such as studying the relationship between AMU and AMR, these data should be collected as close as possible to the point of antimicrobial administration to the animal or population of animals, along with information that provides greater context for its use, such as animal health status at the time of administration, i.e., at the time of prescribing, authorizing, administering, and delivering for administration (but not sales of the antimicrobial).

In general, a core AMU dataset can be generally broken down into two broad components: numerator information and denominator information. Numerator data are the quantities of antimicrobial drugs administered to animals. Denominator information includes data on the animals receiving the drug(s), such as weight, number of animals, patient visits, animal age or production class. From these components, a variety of AMU metrics may be calculated and analyzed, such as number of regimens, total grams per unit animal, grams/animal/year, percentage of operations that treat, rates of antimicrobial use per week and per patient visit, etc.

The following list of data and metadata elements are considered “core information” and are separated below into “numerator information”, “denominator information”, and additional metadata or treatment outcome information to provide additional context to AMU information. (Merge here with following paragraph).



DISCUSSION HIGHLIGHTS

Availability and format of antimicrobial use data is highly variable across different veterinary settings and animal production settings and species. The intent is not to treat all AMU data the same across sectors or to make direct comparisons across species.

The information in the list below is not intended to be exhaustive. For example, AMU information that is available may be constrained by the type of data source, such as health records, treatment logbooks, delivery notes, pharmacy records, discharge records, patient, or farm invoice information.



DISCUSSION HIGHLIGHTS

Gathering the correct data elements is important for understanding AMU trends in food-producing animals. To understand what data elements are collected, participants discussed the numerator, denominator, and additional contextual information data elements that they or their organization may have access to.

During the discussion, concerns such as standardization and varying availability of data elements were raised. Capturing standardized data elements across all sectors will be challenging or, in some cases, simply not possible. For example, naming conventions for drug names/identifiers differ across species. Some sectors have access to these data, but the units in which the data are collected differs across the sectors and farms. For example, differences include the size of the species (small vs. large animal) and how species are grouped (flock vs. individual animal). Data availability is impacted by variations in how data are collected, maintained, and reported among species and individual farms.

Numerator Information

The numerator of AMU data indicating the amount of antimicrobials being administered to the animals, may include the following data elements:

- Name/identifier⁷ of antimicrobial drug prescribed, administered, or currently receiving, authorized, delivered, or purchased
- Indication for use (e.g., extra-label drug use versus approved use, primary visit reason, veterinary service, chief complaint)
- Dosing information (e.g., concentration, frequency, route of administration)
- Total amount administered (mg, kg, etc.)
- Duration of use (e.g., treatment length)

Numerator Data elements each sector has access to:

NUMERATOR DATA ELEMENT	HAVE ACCESS TO (YES / NO / MAYBE)			
	POULTRY (CHICKEN AND TURKEY)	BEEF CATTLE	DAIRY CATTLE	SWINE
Antimicrobial drug name/identifier	Yes	Yes, but no standardization	Maybe	Yes, encouraged through Pork Checkoff
Indication for use	Yes	Yes, but variable	Maybe	Yes, encouraged through Pork Checkoff
Dose information (e.g., concentration, frequency, route of administration etc.)	Yes	Yes, but variable	Maybe	Yes, encouraged through Pork Checkoff

⁷ AMU data should identify specific API being used, so it would be easy to distinguish between medically important antimicrobial and non-medically important antimicrobials. If data (across various drugs) are aggregated, the information would need to separate medically important from non-medically important based on current criteria.

Total amount administered (mg, kg, etc.)	Yes	Yes, but variable	Maybe	Yes, encouraged through Pork Checkoff
Duration of use (e.g., treatment length)	Yes	Yes, but variable	Maybe	Maybe

Denominator Information

The AMU data denominator measures the animal populations that are administered antimicrobial drugs to treat, control, or prevent disease, including the following data elements:

- Animal production subclass/type (broiler vs. layer, beef vs. dairy, nursery swine vs. breeding stock, etc.) w/or animal signalment (age, sex, species, breed)
- Animal weights at time of treatment (e.g., average weight at treatment, slaughter weights, carcass weights, static weights, changing weights)
- Animal demographic information (e.g., animal age or stage of production at time of treatment, animals imported or exported from country)
- Number of animals treated in population (farm, pen, cage level, flock level, hospital or practice level, etc.)

Denominator Data elements each sector has access to:

DENOMINATOR DATA ELEMENT	HAVE ACCESS TO (YES / NO / MAYBE)			
	POULTRY (CHICKEN AND TURKEY)	BEEF CATTLE	DAIRY CATTLE	SWINE
Animal species production subclass/type (broiler vs. layer, beef vs. dairy, nursery swine vs. breeding stock, etc.)	Yes, except for breeder data	Yes	Yes	Yes, encouraged through Pork Checkoff
Animal population numbers	Yes	Yes	Yes	Yes, encouraged through Pork Checkoff
Animal weights at time of treatment (e.g., average weight at treatment; slaughter weights; carcass weights; static weights; changing weights)	Age at time of treatment	Yes, variable	Maybe	Age at time of treatment but not animal weight
Animal demographic information	Yes	Yes	Yes	Yes, encouraged through Pork Checkoff
Number of animals treated in population (farm, pen, cage level, etc.)	Yes, data are provided in flocks, not by individual animal	Yes, variable	Maybe	Yes, encouraged through Pork Checkoff

Additional Contextual Information and Metadata

Numerous factors can influence the need for antimicrobials to protect animal health. Veterinarians and producers can learn from the experience of others to help better delineate steps to control infections and improve judicious antimicrobial use. To help achieve this, it would be very helpful to have additional contextual information which may include details on:

- Animal health status (quantitative and/or qualitative)
 - Information about what disease(s) is/are being treated, controlled, or prevented.
 - Information about disease burden (incidence or prevalence information).
 - Diagnostic testing type or diagnostic testing information
- Treatment outcomes (success, failure, subsequent treatment regimens, other production/performance indicators at harvest)
- Temporal aspects of data collection, such as use across weeks, months, years, or production stages
- Any relevant information to provide AMU context (e.g., biosecurity measures on farm, vaccination status of animal population, national or regional outbreaks (HPAI, wildfires)
- Information characterizing the extent to which data collected are representative of a species or sector in the U.S.

Data elements each sector has access to:

ADDITIONAL CONTEXTUAL DATA ELEMENTS	HAVE ACCESS TO (YES/NO/MAYBE)			
	POULTRY (CHICKEN AND TURKEY)	BEEF CATTLE	DAIRY CATTLE	SWINE
Animal health status, quantitative and/or qualitative information about disease(s) being treated, controlled, or prevented and Information about disease burden, e.g., incidence or prevalence information	No	Maybe	Yes	Maybe
Treatment outcomes	No	Maybe	Maybe	Maybe
Temporal aspects of data collection	Reported annually	Maybe		Maybe
Any relevant information to provide antimicrobial use context		Maybe	Yes	Maybe
Information characterizing the extent to which data collected are representative of the particular food producing species or commodity in the US.	Yes	Maybe	Maybe	Maybe

Reporting Structure



DISCUSSION HIGHLIGHTS

While the PPP is not meant to establish thresholds or performance standards, working group participants expressed concerns about the de facto establishment of thresholds or performance standards derived from PPP reports. There was concern that individual producers may choose to adhere to those thresholds, instead of focusing on animal health and welfare. Also, concern was expressed that purchasers may require producers to submit AMU data to the repository as a condition of sale and/or may choose not to purchase from producers who do not meet a certain threshold or performance standard.

It was agreed that reporting of AMU data should be released on an annual basis, recognizing that collection of AMU data will be done on a rolling basis, as data become available. One challenge that was raised is that collecting, anonymizing and reporting data at the state level or regional level is challenging and perhaps impossible. The movement of animals across state lines complicates state level data collection, and there may also be concerns about protecting data confidentiality.

Under the PPP, a structure for proactive public reporting of summary AMU data would be developed by the DRC, with input from the Steering Committee and FDA. This could be in the form of a website showing summary reports or an interactive dashboard display of charts/tables. The reporting would provide information on AMU across diverse sectors of veterinary medicine and animal production and be transparent about the methodologies used to collect and analyze the data. The DRC would be the primary entity responsible for summarizing the collected AMU data, including information providing adequate context for AMU, appropriate AMU metrics, and national or regional trends over time.

Potential reports and reporting elements include:

- Public-facing periodic or annual progress reports and/or dashboards containing aggregated and summarized, de-identified AMU data. These reports would include national trends over time.
- Metrics of progress for long-term AMU data collection under the PPP (e.g., number of data sharing agreements, AMU data repository development milestones over time, and other metrics of success or areas for future growth or progress).
- Any publications or research products from special work streams.

APPENDIX I

ANTIMICROBIAL USE DATA REPOSITORY PUBLIC-PRIVATE PARTNERSHIP

Draft Principles

Starting in late 2021, the FDA Foundation launched phase 1 of this work and facilitated discussion on the feasibility of setting up a public-private partnership (PPP) to track and monitor antimicrobial use with 30 stakeholders, including food-producing animal trade associations, researchers, academics, consumer advocacy groups, and government agencies. These meetings were conducted through one-on-one conversations, a roundtable discussion, and a public meeting. Key themes from one-on-one discussions were used to inform the following draft principles to support a PPP.

PURPOSE AND INTENDED OUTCOMES

- **Monitoring of antimicrobial use** in food-producing animals can lead to a **better understanding of the public health 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. These 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 are 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.

APPENDIX II

WORKING GROUP PARTICIPATING ORGANIZATIONS

American Association of Bovine Practitioners

American Association of Swine Veterinarians

American Veterinary Medical Association

Kansas State University College of Veterinary Medicine

National Cattlemen's Beef Association

National Milk Producers Federation

National Pork Producers Council

National Pork Board

National Turkey Federation

North American Meat Institute

University of Minnesota Department of Veterinary and Biomedical Sciences

University of Minnesota Department of Veterinary Population Medicine

US Poultry & Egg Association

***Disclaimer:** While the stakeholders above participated in the discussions that led to this report, their participation does not imply endorsement of the report.*

APPENDIX III

BACKGROUND FOR POTENTIAL FRAMEWORK FOR A PUBLIC-PRIVATE PARTNERSHIP

Antimicrobial resistance (AMR) is recognized as a growing global health threat requiring coordinated antimicrobial use (AMU) stewardship actions across multiple sectors, including human, animal, and environmental health. Measuring the impact of antimicrobial stewardship activities is critical to understanding the relationship between AMU and AMR and to further promote responsible use of antimicrobials in animals across diverse veterinary and animal production sectors.

FDA efforts to collect and analyze data related to AMU include:

- In 2018, FDA CVM released [Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019–2023](#). This plan outlined CVM’s intended focus on support of antimicrobial stewardship along three key goals: 1) align antimicrobial drug product use with the principles of antimicrobial stewardship, 2) foster stewardship of antimicrobials in veterinary settings, and 3) enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals.
- FDA collects annual sales and distribution data estimated by major food-producing species (under Section 105 of the [Animal Drug User Fee Amendments of 2008 \(ADUFA\)](#)).
- FDA published a [concept paper](#) for public comment in 2017 that proposed the use of a biomass denominator to adjust annual data on the amount of medically important antimicrobials sold for use in food-producing animals in the United States. In 2022, FDA launched an [Interactive Summary of Biomass-Adjusted Antimicrobial Sales Data](#) for years 2016 to 2020.
- In addition to the collection of antimicrobial sales data, FDA monitors AMR trends through the [National Antimicrobial Resistance Monitoring System \(NARMS\)](#).
- FDA supports ongoing data collection efforts to gather information on antimicrobial use and stewardship practices on farms through programs such as the [USDA Animal and Plant Health Inspection Service’s National Animal Health Monitoring System \(NAHMS\)](#).
- FDA funded four cooperative agreements for AMU data collection in food-producing animals (2 grants funded since 2016) and in companion animals (2 grants funded since 2020). These pilot data collection efforts are expected to be funded for up to 5 years and are intended to provide part of the baseline information on AMU practices and important information on methodologies to help optimize long-term strategies for collecting and reporting such data.

A key data gap is the limited availability of AMU data in animals, and there is a need to develop a long-term strategy for implementing a functional and efficient infrastructure for collecting data about the use of antimicrobials in animals across diverse veterinary and animal production sectors.

1333 New Hampshire Ave, NW
Suite 420
Washington, DC 20036

reaganudall.org