



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

---

**The broadcast will begin shortly**

June 14, 2022  
1-3 pm Eastern Time

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 \$65,329 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](https://www.fda.gov).



# Welcome

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

# Thank you for joining



This webinar is being recorded. The slides, transcript, and video recording will be available on the FDA Foundation website after the meeting.



If you'd like to ask a question, you may enter it in the Zoom Q&A. We will get to as many questions as time allows.



Speakers will not address questions regarding any pending regulatory action or discuss specific companies or medical products by name.



Your microphone and video will remain off during the meeting. Those who registered to present public comment will be unmuted when it is their time to speak. Reminder: public commenters should check in by 1:30 pm ET.

# Agenda



- 1 p.m.\*** Welcome
- 1:05 p.m.** Opening Remarks from U.S. Food and Drug Administration
- 1:15 p.m.** The Value of Data
- 1:50 p.m.** A Roadmap to a Public-Private Partnership
- 2 p.m.** Public Comment
- 3 p.m.** Adjournment

\*Eastern Time



# Submit Your Comments to the Docket



FDA has opened a docket to accept public comments through August 21, 2022 on the report and general insights into the collection of antimicrobial use data in food-producing animals.

Visit [www.regulations.gov](https://www.regulations.gov) and search for docket **FDA-2022-N-0824**.



# Opening Remarks

**William T. Flynn, DVM, MS**

Deputy Director, Science Policy

Center for Veterinary Medicine

U.S. Food and Drug Administration

# **Tracking and Monitoring Antimicrobial Use in Food-Producing Animals**

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

**Virtual Public Forum  
Tuesday, June 14, 2022  
1-3pm Eastern Time**

**William T. Flynn, DVM, MS  
Deputy Director for Science Policy  
FDA Center for Veterinary Medicine**

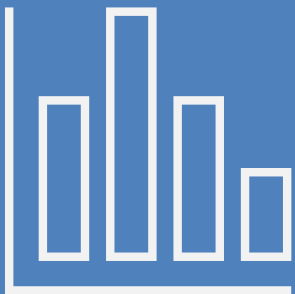
# Antimicrobial Stewardship



- CVM's 5-year antimicrobial resistance action plan is focused on "*Supporting Antimicrobial Stewardship in Veterinary Settings*"
- Focus of stewardship on how antimicrobials are used
- Use data is needed to inform stewardship efforts



# Currently Available Data



## Sales and Distribution Reports

- Represents volume distributed, but not necessarily volume used.
- Does not provide information on reason for use.
- Products are approved for multiple animal species; species data are estimates.

## Challenge

- Need for data that better reflects actual use
- Lack of existing infrastructure for coordinated system for collecting antimicrobial use (AMU) data across agricultural and veterinary sectors.

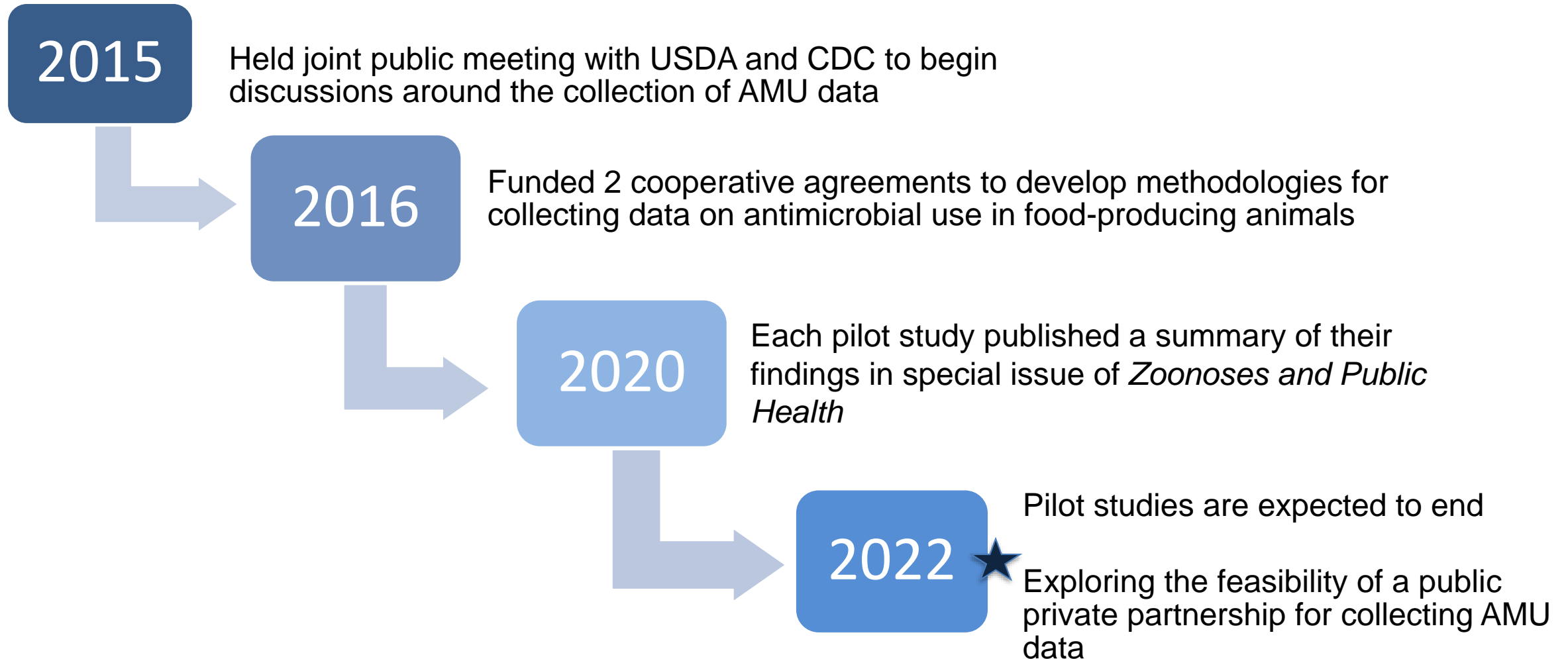
# Why is AMU Data collection important?

Establishing a system for collecting representative data on antimicrobial use in animals would benefit public and animal health by:

- Enable monitoring of trends; enhance understanding of AMR drivers
- Fostering antimicrobial stewardship
- Informing regulatory and policy decision making
- Enhancing transparency regarding antimicrobial use



# Prior Efforts to Explore Potential Strategies



# Today's Public Forum

- Thank you for your participation - your input is critical
  - FDA has also opened a docket to accept public comments through August 21, 2022
- Today's input (and that submitted to docket) will inform next steps; we expect more stakeholder engagement as we further develop a plan
- We look forward to a productive discussion today



# The Value of Data



## Moderator

**Susan C. Winckler, RPh, Esq.**

## Panelists

**Mike Murphy, DVM, JD, PhD**  
American Veterinarian Medical Association

**Paul Plummer, DVM, PhD**  
Iowa State University

**Randall S. Singer, DVM, MPVM**  
University of Minnesota

**David Wallinga, MD, MPA**  
Natural Resources Defense Council



# A Public Health Imperative.....

---

A bleak global future, driven by antibiotic use

- Superbug infections as the leading cause of death, by 2050
- From 1.3 million to 10 million *annual* deaths, across the world
- *US deaths between 35,000 and 162,000 today. By 2050 ???*

## Links:

Wallinga et al. **Review of the Effectiveness of Current US Policies on Antimicrobial Use in Meat and Poultry Production**, *Curr Env Health Reports*, June 2022, DOI: [10.1007/s40572-022-00351-x](https://doi.org/10.1007/s40572-022-00351-x)

Laxminarayan, **The overlooked pandemic of antimicrobial resistance**, Feb. 22, 2022, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8769677/pdf/main.pdf>

Antimicrobial Resistance Collaborators. **Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis**, *Lancet* Jan 20, 2022. DOI: [10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

Tiseo et al., **Global Trends in Antimicrobial Use in Food Animals from 2017 to 2030**, DOI: [10.3390/antibiotics9120918](https://doi.org/10.3390/antibiotics9120918)

## ...Driving An Imperative to Closely Track Use

- Antibiotic use, and especially overuse, is what drives the spread of antibiotic resistance. (See links)
- Comprehensive tracking and transparent reporting of antibiotic prescribing and use is essential, in order to:
  - ✓ Identify ongoing patterns of overuse.
  - ✓ Inform effective government actions to reduce or eliminate them.
  - ✓ Help hold prescribers accountable.
  - ✓ Hold FDA accountable for meeting the public health imperative to reduce overuse as much as possible.

### Links:

O'Brien TF (2002). **Emergence, spread, and environmental effect of antimicrobial resistance: how use of an antimicrobial anywhere can increase resistance to any antimicrobial anywhere else.** *Clin Infect Dis*. DOI: [10.1086/340244](https://doi.org/10.1086/340244).

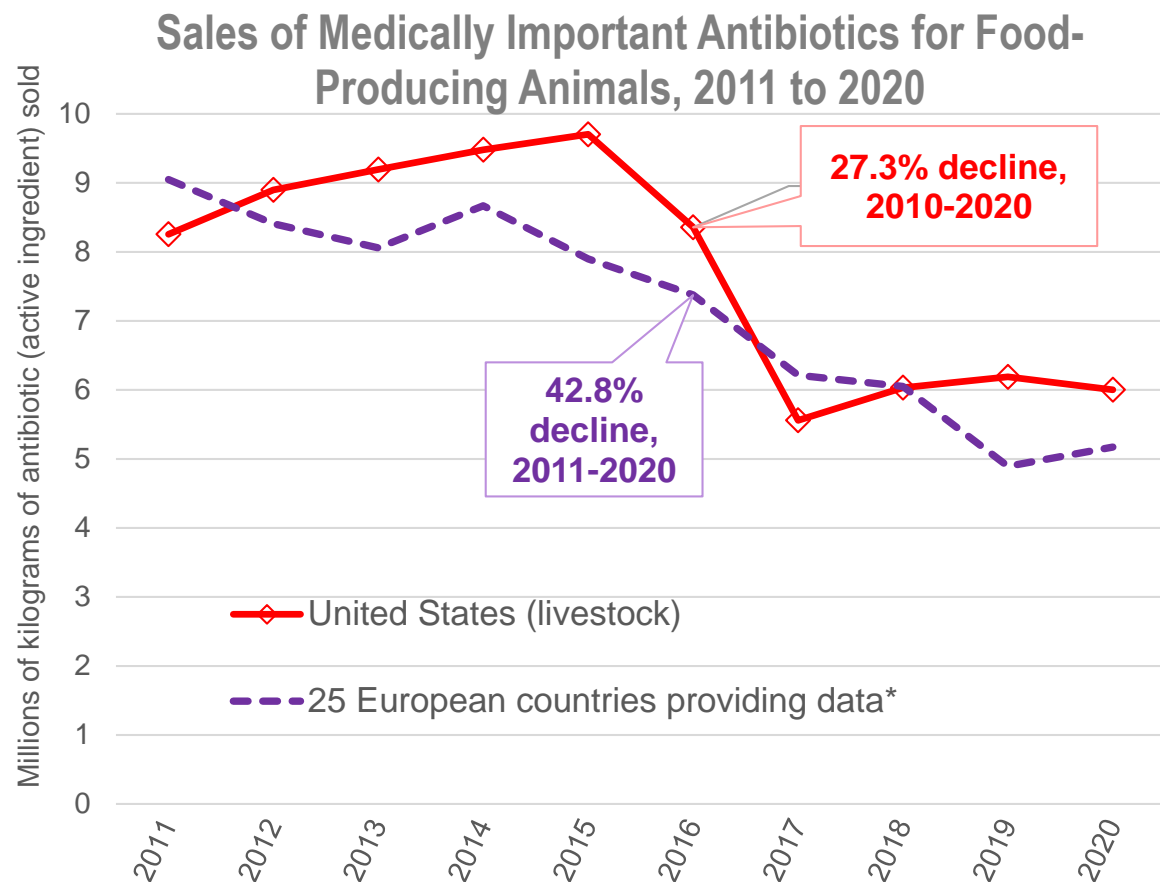
European Medicines Agency (2011), **Trends in the sales of veterinary antimicrobial agents in nine European countries (2005-2009)**, [https://www.ema.europa.eu/en/documents/report/trends-sales-veterinary-antimicrobial-agents-nine-european-countries\\_en.pdf](https://www.ema.europa.eu/en/documents/report/trends-sales-veterinary-antimicrobial-agents-nine-european-countries_en.pdf).

Shallcross LJ, Davies DS. **Antibiotic overuse: a key driver of antimicrobial resistance.** *Br J Gen Pract*. 2014;64(629):604-605. DOI: [10.3399/bjgp14X682561](https://doi.org/10.3399/bjgp14X682561)

European Commission (2015), **COMMISSION NOTICE. Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)**, [https://ec.europa.eu/health/system/files/2016-11/2015\\_prudent\\_use\\_guidelines\\_en\\_0.pdf](https://ec.europa.eu/health/system/files/2016-11/2015_prudent_use_guidelines_en_0.pdf);

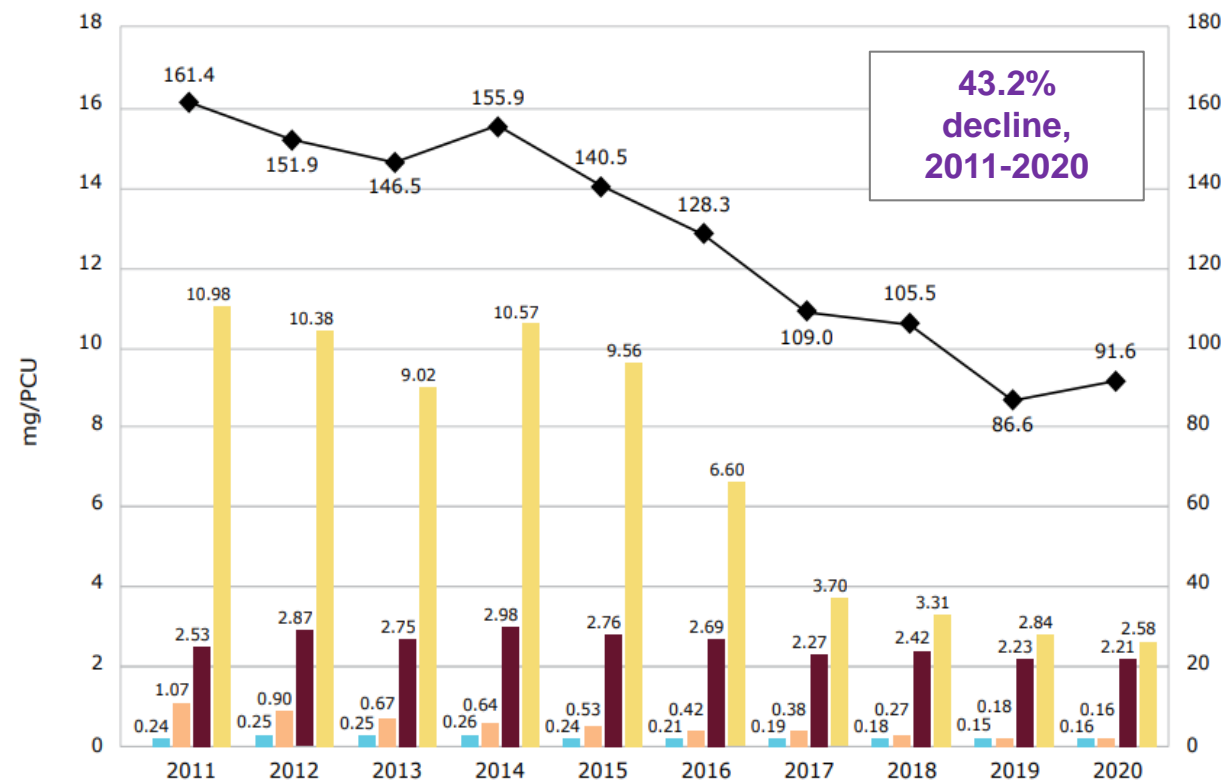
World Health Organizations (2020), Antibiotic Resistance, July 31, 2020, <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>

# Antibiotic Sales are Entirely Appropriate as a Proxy for Use



Sources: European Medicines Agency, ESVAC project, **Interactive ESVAC database**; FDA, **Annual ADUFA Summary reports on antimicrobials sold or distributed for use in food-producing animals, 2011-2020**, <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-reports>

## Use of Medically Important Antibiotics in Food-Producing Animals in 25 European Countries\*, 2011-2020



\* Includes all top European livestock producers except Romania. Also not included are Malta, Luxembourg, Switzerland, Croatia, and Greece

European Medicines Agency, *Eleventh ESVAC Report, Trends from 2010 2020*



# A Roadmap to a Public-Private Partnership

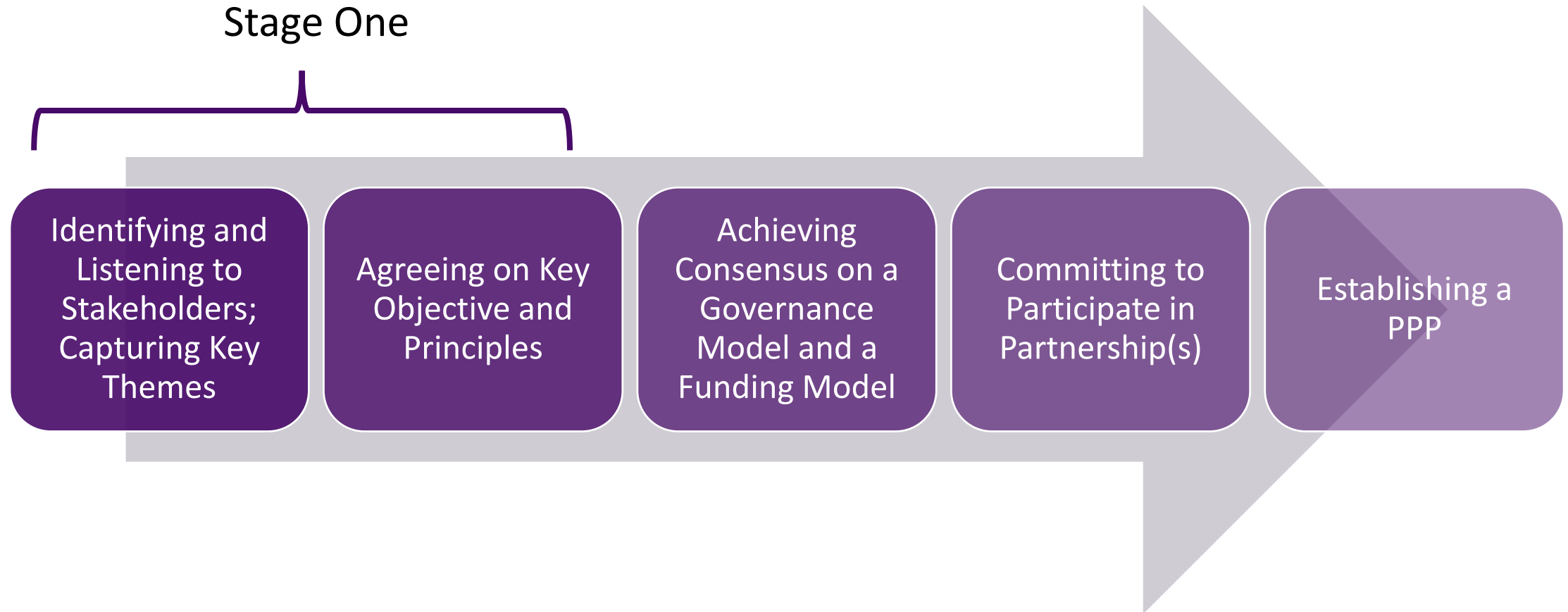
**Amar Bhat, PhD**

Chief Operating Officer

Reagan-Udall Foundation for the FDA

# Roadmap to a PPP

## Stage One



# Key Themes

The following key themes emerged from our discussions with stakeholders:

- 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.



# Key Objective



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

# Draft Principles

REAGAN-UDALL  
FOUNDATION  
FOR THE FDA

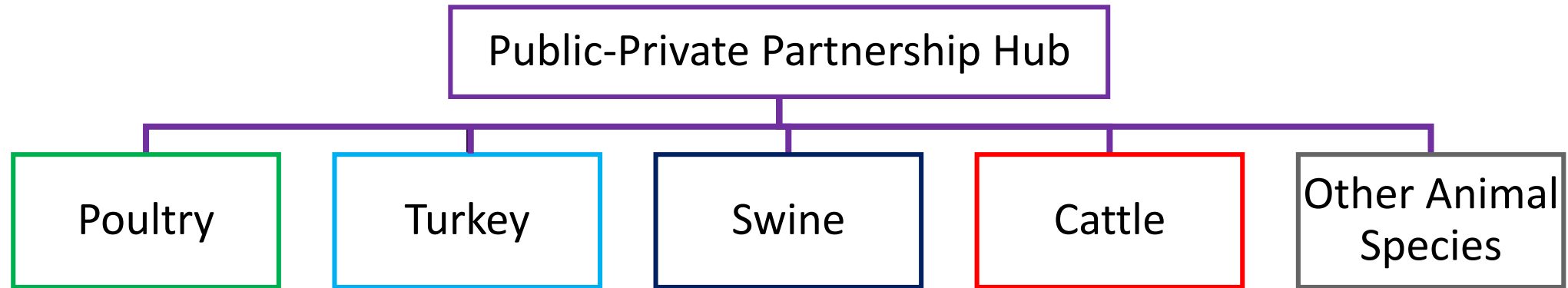
## Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals



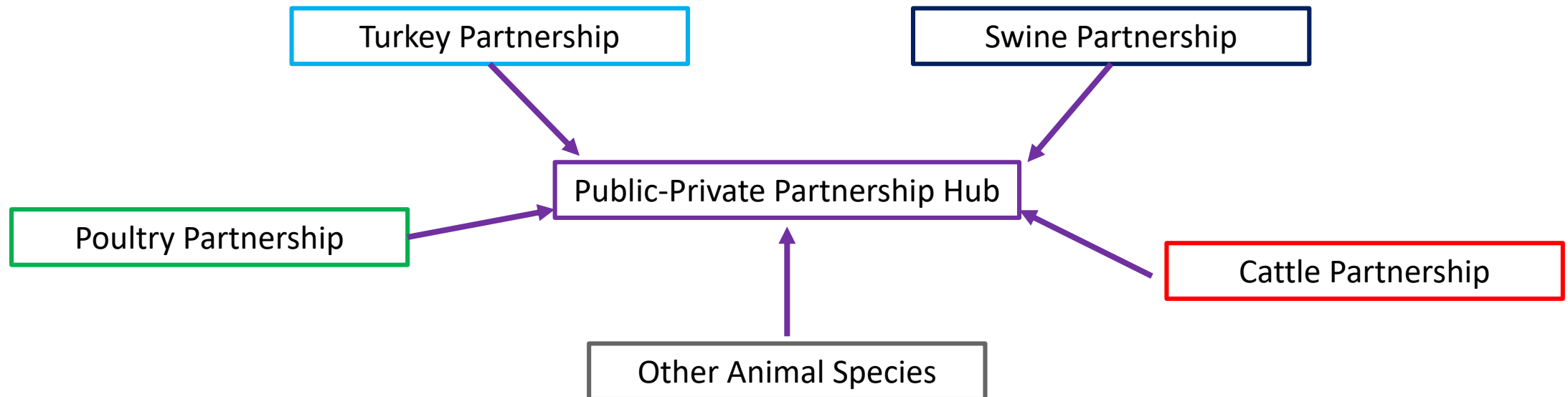
Initial Report | May 2022

# Potential Governance Models

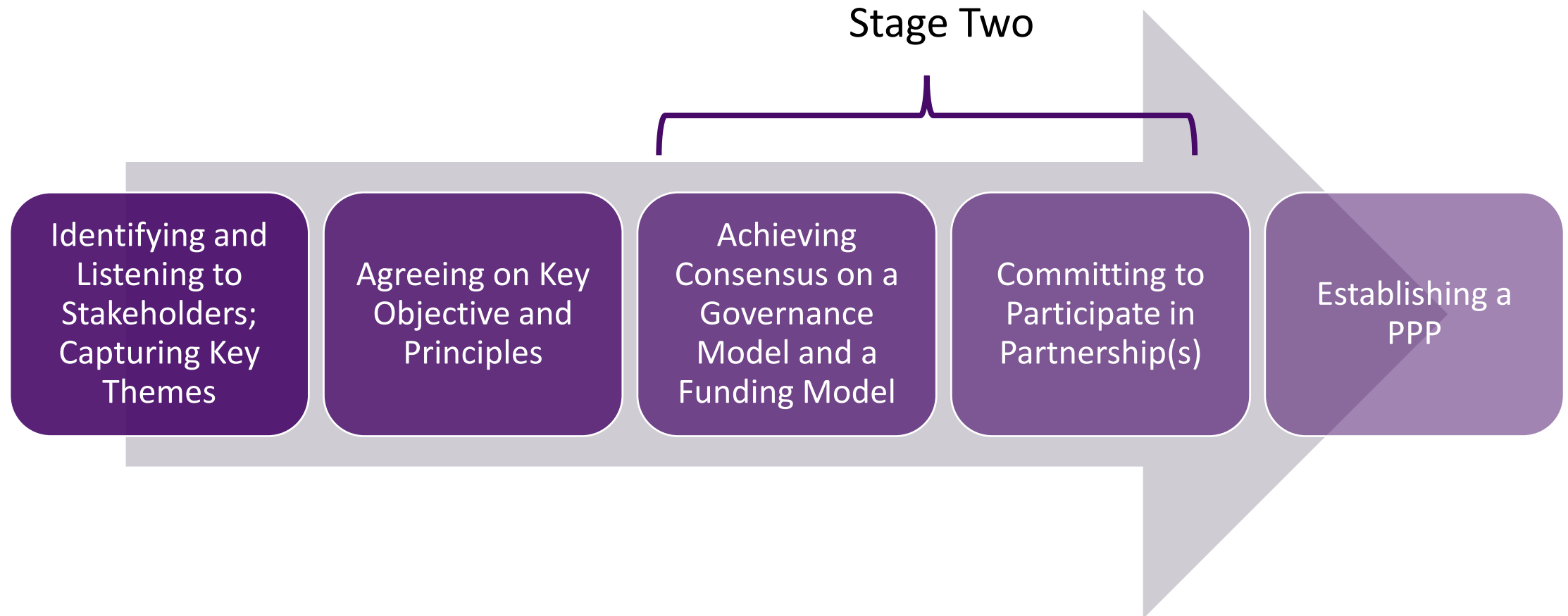
Model 1: One Public-Private Partnership where each animal commodity compiles data and shares analyses at its own pace, but according to common governance approaches.



Model 2: Multiple Partnerships, with varying governance approaches, Feeds into an overall Partnership Hub.



# Roadmap to a PPP



# Public Comment

PLACEHOLDER FOR COUNTDOWN CLOCK



# Thank You!