

Accelerating Health Through 1Data

How To Share and De-Risk Data: Data Agreements

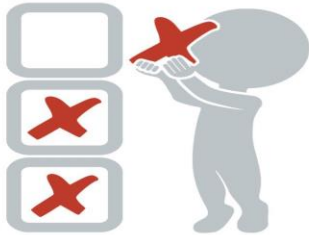


Paul R. Lowe
March 27, 2019

"Torture the data, and it will confess to anything."
– [Ronald Coase](#), winner of the Nobel Prize in
Economics

Background

- Data is often a necessary component or the result of research.
- “Data” means a proprietary set of recorded information that is provided by one party to another party for use under defined conditions.
- Data can take many forms, originate from various sources, and have various levels of sensitivity due to a variety of factors. Data can also be held by the Owner has a valued asset.



“Data, I think, is one of the most powerful mechanisms for telling stories. I take a huge pile of data and I try to get it to tell stories.” – [Steven Levitt](#), Co-author of [Freakonomics](#)

Background

A “Data Sharing Agreement”

- Refers to a legally binding agreement, separate from a sponsored research or Material Transfer Agreement, which at least...
 - Defines the Data
 - The terms and conditions of use of the Data
 - The rights and obligations of the parties related to the use of the Data
- The Data Sharing Agreement is both a means of informing the Data Steward or User of requirements regarding the Data and a means of obtaining the Data Steward or User's agreement to abide by these requirements.

Background

- To determine whether Data can be shared, the Data Contributor/Provider needs to know:
 - Where the Data came from, e.g., derived from laboratory tests, results from interviews with human study participants, patient outcomes, drug performance; provided by others;
 - Who needs or wants the Data, e.g., students, clinicians; academic researchers;
 - What does the User want to do with the Data, e.g., comparative research, validation, marketing, patient support, drug development;
 - What institutional, legal or regulatory requirements related to the provision of Data, e.g., HIPAA, Common Rule, Export Controls, are applicable;
 - What is the proprietary value of the Data to the Data Contributor/Provider, e.g. a database that would be costly to replicate, potential unrealized IP created solely through Data analysis
 - What other contractual conditions restrict the Data Contributor/Provider from sharing the Data with User, e.g., developed under contract where third-party obligations may exist

Background

- The Data Steward and/or User also needs to answer some questions to determine if they can receive and use the Data:
 - What Data is needed to accomplish a desired purpose, e.g., aggregate data or source data, personally identifiable or de-identified data;
 - Requires Data Steward or User to determine requisite data controls to ensure proper stewardship and security
 - What is the scope of the intended use, e.g., research only, commercial use, redistribution;
 - Who will need access to the Data, e.g., requestor's team only, students, other researchers, subcontractors;
 - What legal or regulatory requirements related to use of the Data are in place, e.g., Institutional Review Board (IRB) approval, Privacy Board approval under HIPAA, license under export control regulations;
 - Which portions of the Data will need to be disclosed if the User publishes results of their use of the Data;
 - What are the data security requirements/expectations – can they be met?, e.g., some data may be proprietary, while other Data is not

Background - Convergence of Expectations

- Once the Data Contributor/User have converged on what Data is being shared and the scope of use, then Data security provisions need to be considered, such as:
 - ✓ Authorization or privilege management – identification of individual Users who are allowed to use the Data
 - ✓ Authentication or identify management – confirmation that the authorized User is really the authorized User and confirmation that all approvals are in place; and
 - ✓ Monitoring and enforcement – validation and assurance that use of the Data is consistent with authorized use and conditions of use such as keeping certain Data separate from other Data, protecting the integrity of the original Data, in a secure location, or not on a linked computer
 - ✓ Data Protection – instructions regarding any special infrastructure required to store and restrict access to the Data (dedicated and isolated servers and lock-cabinets); special control processes to protect the integrity of the Data, track the location(s) of the Data, track the release of the Data and the reasons for the release; archiving and/or disposing the Data at the prescribed times and in the prescribed manner, as established by agreement.

- The 1Data Data Sharing and Use Agreements include:
 - A clear description of the Data to be provided
 - The permitted uses for the data and any regulatory requirements that the Data Contributor/Provider needs to have in place
 - The names or general descriptions of individuals who can access or receive the Data (“1Data Investigators”)
 - Conditions under which the User can provide the Data to other Users (“Data Recipients”) and under what conditions

- The 1Data Data Sharing and Use Agreements include:
 - The length of time the Data may be retained or used
 - The method of Data disposal at the end of the Data Sharing and Use period (returned or destroyed)
 - The 1Data Investigator and Data Recipient's obligations regarding new data generated based on the Data originally provided
 - The management of new intellectual property created using the Data

- The 1Data Data Sharing and Use Agreements include:
 - Instructions on how the Data should be aggregated, encrypted, tagged (proprietary or non-proprietary), anonymized, de-identified, “cleaned”
 - Safeguards required to protect confidential, private, sensitive information
 - The process for review by the Data Contributor/Provider of draft publications resulting from the use of the Data
 - Practical aspects of the Data transfer
 - Statement of ownership of the Data, if it is proprietary, and the provenance and authenticity of the Data, if that requires confirmation

The 1Data Contribution Process

- Master Data Sharing Agreement
 - Used to establish the legal requirements between a Data Contributing Organization (“DCO”) and Kansas State University and the University of Missouri – Kansas City for the stewardship of Data contributed to the 1Data Initiative
 - Reflects the input of several of the 1Data Initiative Data Contributors
 - Will serve as the static contracting vehicle to memorialize the transfer and stewardship of all Data provided for the 1Data Initiative
 - Includes sections and attachments to address all of the components detailed on the previous slides
 - Each Agreement requires the signature of authorized representatives from the Data Contributing Organization, Kansas State University and the University of Missouri-Kansas City

The 1Data Use Process for Third-Party Users

- Data Use Agreement
 - Used to establish the legal requirements between Kansas State University (representing the 1Data Initiative) and another third-party entity that is not a 1Data Investigator (“Data Recipient” or “1Data Affiliate”) requesting access to Data
 - Flows down certain requirements of the Master Data Sharing Agreement
 - Limits the use of the Data to non-commercial research purposes
 - Does not allow access to core data structures and has limits placed on queries, such that they do not have access rights and cannot access the DCO Data without permission coordinated by 1Data Investigators, DCOs, and K-State and UMKC representatives
 - Each Agreement requires the signature of authorized representatives from the Data Use Organization and Kansas State University

The 1Data Use Process

- Research Request/Authorization
 - Used to approve a specific use of Data for research to be performed by a non-1Data Investigator Third-Party Data Recipient
 - May be a Data Recipient who will be required to execute a Data Use Agreement, or a non-affiliated 1Data End User
 - For Non-Affiliated 1Data End Users, access is only allowed for a very limited ability to search the 1Data Platform, that only allows the view of results from queries limited to the number of returned data and general data properties for non-commercial research purposes
 - Does not allow access to core data structures and has limits placed on their queries, such that they do not have access rights and cannot access the DCO Data without becoming a 1Data Investigator or an Affiliated Data Recipient
 - Each Research Request/Authorization requires the prior review and authorization of the DCO(s) and the 1Data Team at K-State and UMKC



“What did you take away from the meeting?”

Questions?

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1DATA

De-risking Data

Joshua Staley

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DATA

DATA

**What does
this mean to you?**

Depends on the data and the data provider

**Human Healthcare
Animal Healthcare
Industry R&D
University R&D**

Protecting you from your data:

Human Healthcare Patient Information

- A. Healthcare Plan
- B. Medications
- C. Symptoms
- D. DOB
- E. Phenotype
- F. Height
- G. Weight
- H. Zip Code
- I. Demographics

i. Name

ii. Address

iii. Contact Info

Animal Healthcare Patient Information (Pet)

- A. Healthcare Plan
- B. Medications
- C. Symptoms
- D. DOB
- E. Phenotype
- F. Height
- G. Weight
- H. Zip Code
- I. Demographics

i. Name (Owner)

ii. Address (Owner)

iii. Contact Info (Owner)

Protecting you from the data:

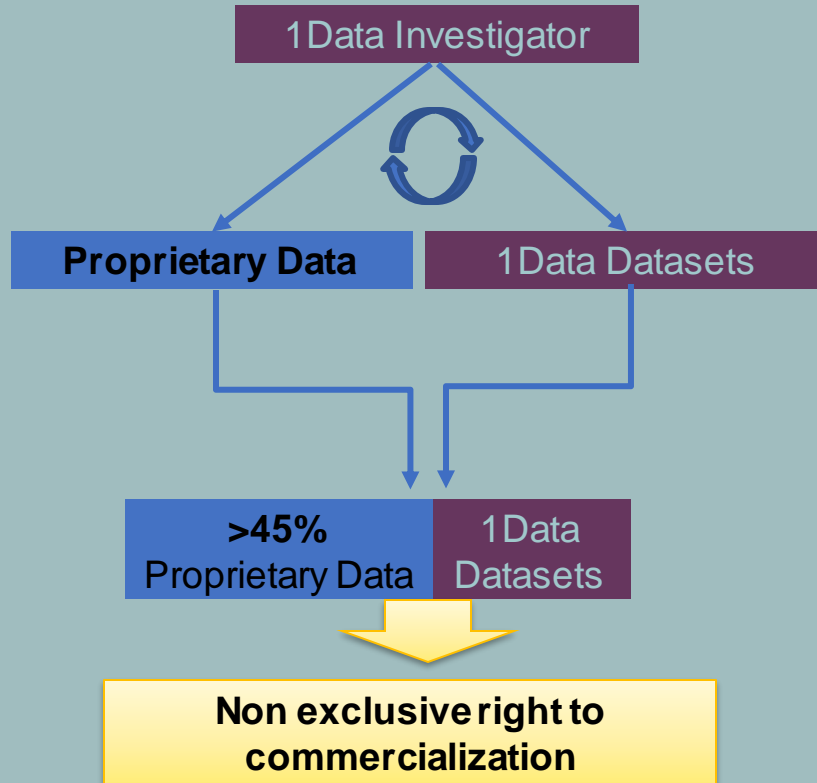
University & Industry R&D

1. ~~Company Name~~
2. Drug Development
 - A. Human / Animals Trails
 - a) Quantity of subjects
 - b) Species (Animal)
 - i. Breed
 - c) Health Information
 - i. Disease
 - i. Symptoms
 - ii. Medication
 - i. PBPK Analysis
 - iii. DOB
 - iv. Race (Human)
 - v. Height

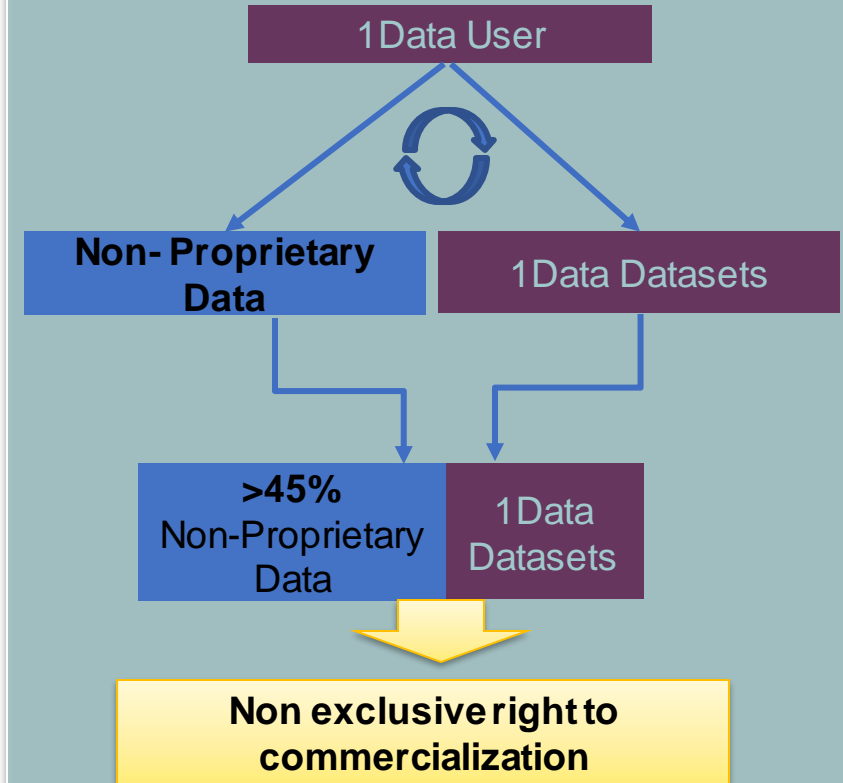
- vi. Weight
- d) Demographics
 - i. ~~Name~~
 - ii. ~~Address~~
 - iii. ~~Contact Info~~
- B. Drug Information
 - i. ~~Structure~~
 - ii. M.W
 - iii. Dosing
 - iv. Side effects
 - v. PK Analysis
- C. Contributors
 - A. Grant Funding
 - B. ~~Venture Capital Funding~~

Protecting your Interest in your data:

Shared Proprietary Data



Shared Non-Proprietary Data



Bottom Line:

**All Data can be
De-risked to the
data providers
specification**

Questions?



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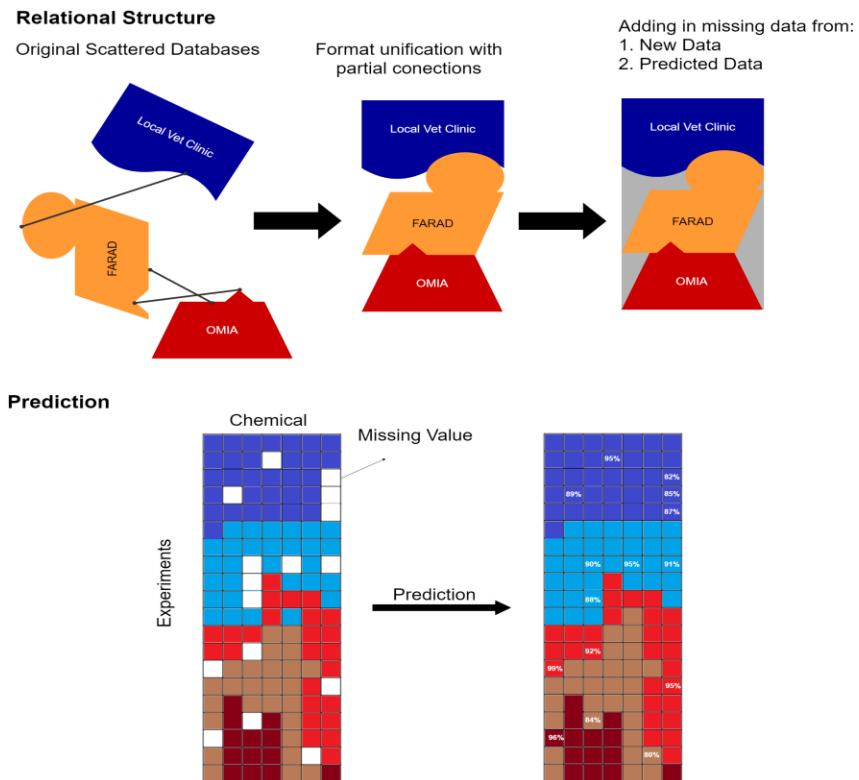
How to Share and De-risk Data: The FARAD Example

Jim E. Riviere, D.V.M., Ph.D.
*Distinguished Professor Emeritus
KSU and NCSU*



What is the Power of a 1Data Platform

- **1Data** creates a *Structured Environment for Animal Data and Simulation* (SEADS), a key enabling technology for regional translational medicine efforts.
- **FARAD** The Food Animal Residue Avoidance and Depletion system is a similar shared multi-sourced data platform focused specifically on chemical food safety that was the partial catalysis for developing SEADS.
- FARAD is now incorporated into SEADS and illustrates power of integrated datasets



FARAD is a consortium for identifying, gathering, extracting, analyzing, generating, and extending residue avoidance information to ensure that animal derived foods will be free of illegal chemical & drug residues and safe for consumers

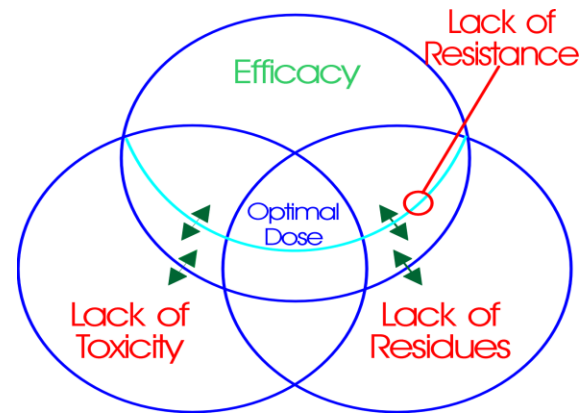
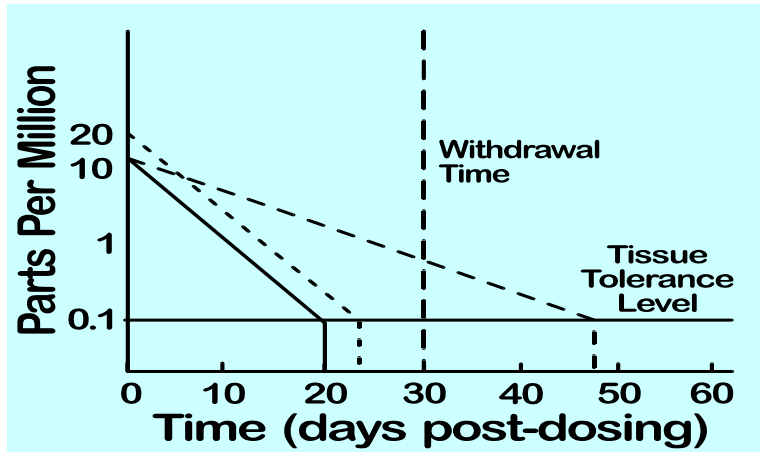
FARAD's Mission

Keeping the Food Supply Safe
by Avoiding Drug, Pesticide and Biotoxin
Residues

Primary Tasks of FARAD

Establish Withdrawal Intervals For:

1. Environmental Contaminants
2. Extra-label Drug Use for Major Animal Species
3. Extra-label Drug Use for Minor Animal Species
4. Bioterrorism



FARAD has developed a pharmacokinetic “toolbox” to deal with these issues

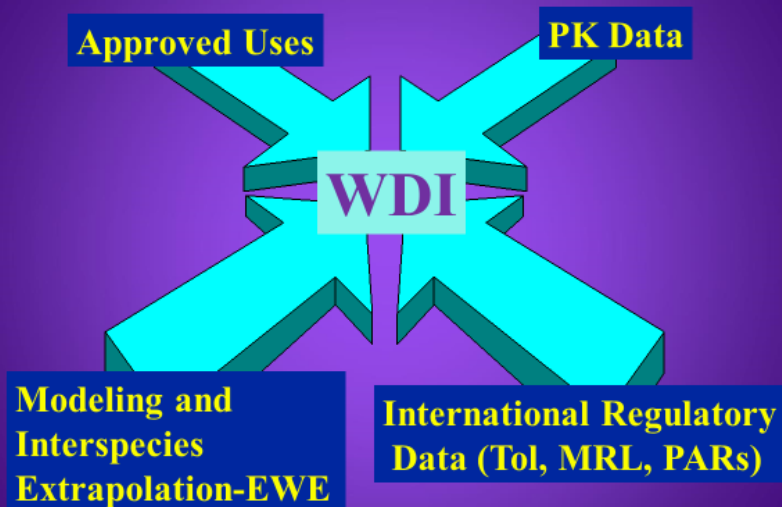
- **Large database of PK parameters**
- **FARAD intranet of computational tools and resources**
- **Historical response data**
- **Two pharmacokinetic modeling approaches to account for changes in physiology and disease**
 - **Population Pharmacokinetic models (Pop PK)**
 - **Physiological Based Pharmacokinetic Models (PBPK)**
- **These PK models allow one to factor in species, breed, age and disease effects on tissue deposition**



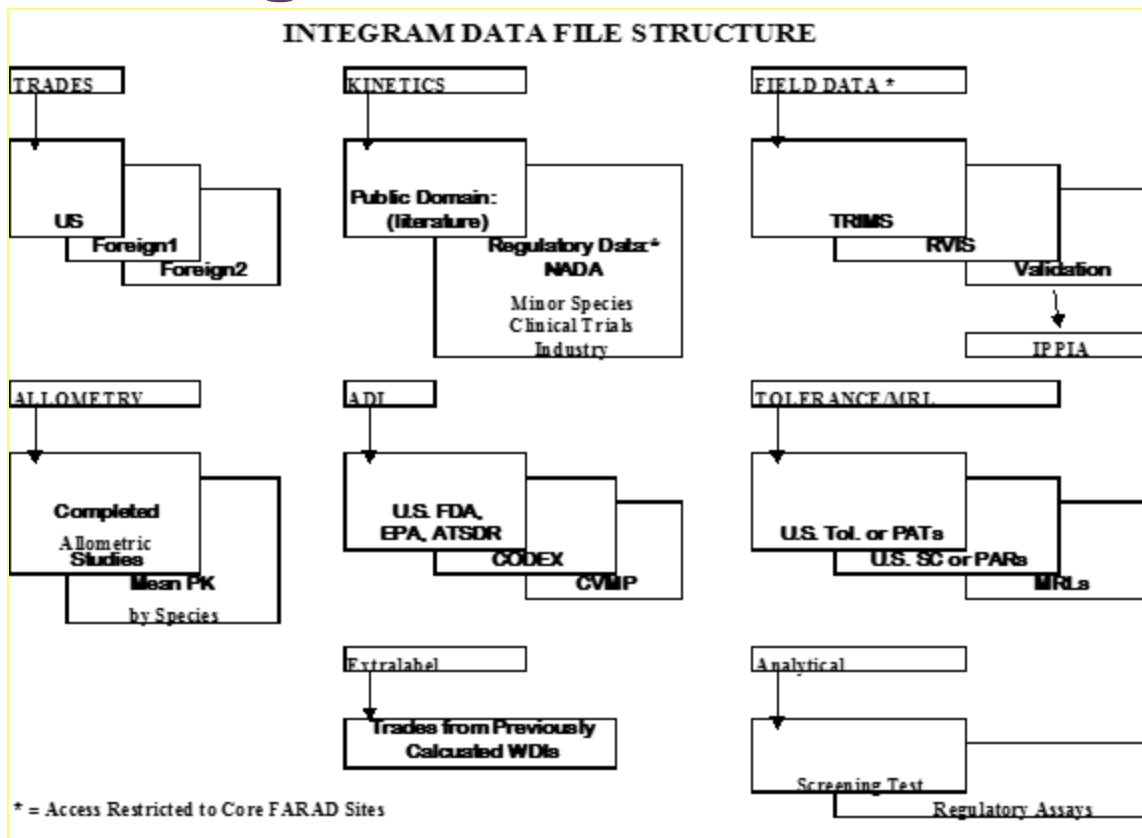
FARAD

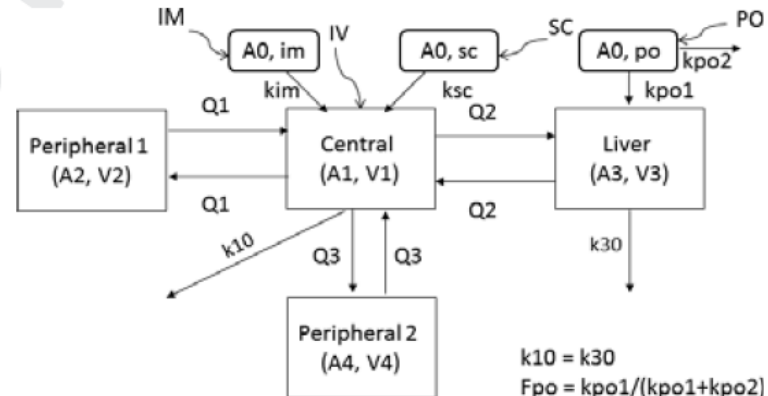
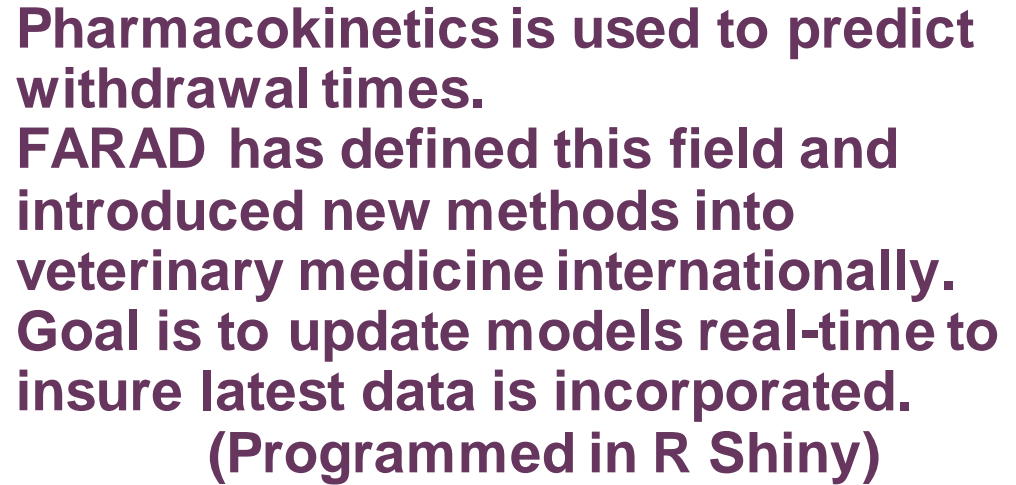
FARAD utilizes a computerized databank of information on chemical residues in food animals. Data are categorized into five major areas:

1. Approved Drugs for Food Animals
2. Tolerances for Residues
3. Pharmacokinetic data
4. Bibliographic Citations
5. Rapid Residue Screening Tests

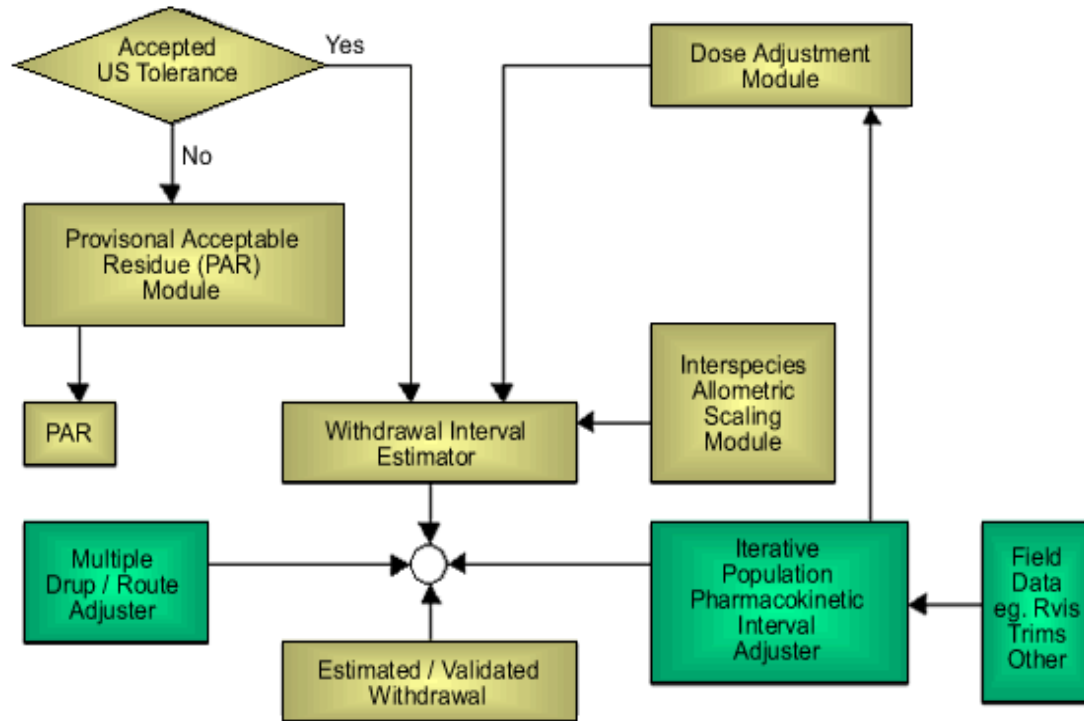


FARAD Integrated Database Structure





Estimated Withdrawal-Interval Estimator (EWE) algorithm



Decision by a “Computer Committee”

Results of these analyses is a list of calculated withdrawal times using all data sources

- Historical response
- Half-Life Dose Multiplier algorithm based on approved withdrawal time adjusting for dose or disease
- Foreign approvals using EWE algorithm
- Population Pharmacokinetic estimate
- Physiological Based Pharmacokinetic model estimate

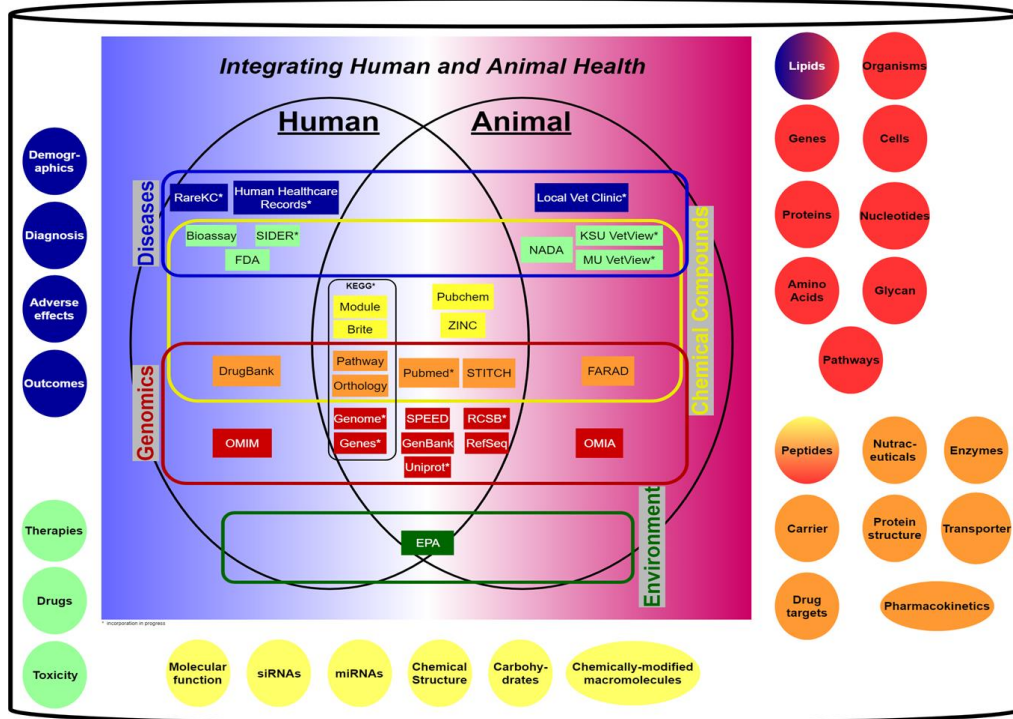
What Enables FARAD to Combine Data

- Congressional mandate and decades of experience builds trust amongst users, data providers and USDA/FDA.
- Pharma shares data under confidentiality agreements which allow us to use data in predictive modelling but not publicly share raw data on open website.
- FARAD has developed intranet controlled by UCD VPN protocols that restricts who gets access to entire database.

Vision

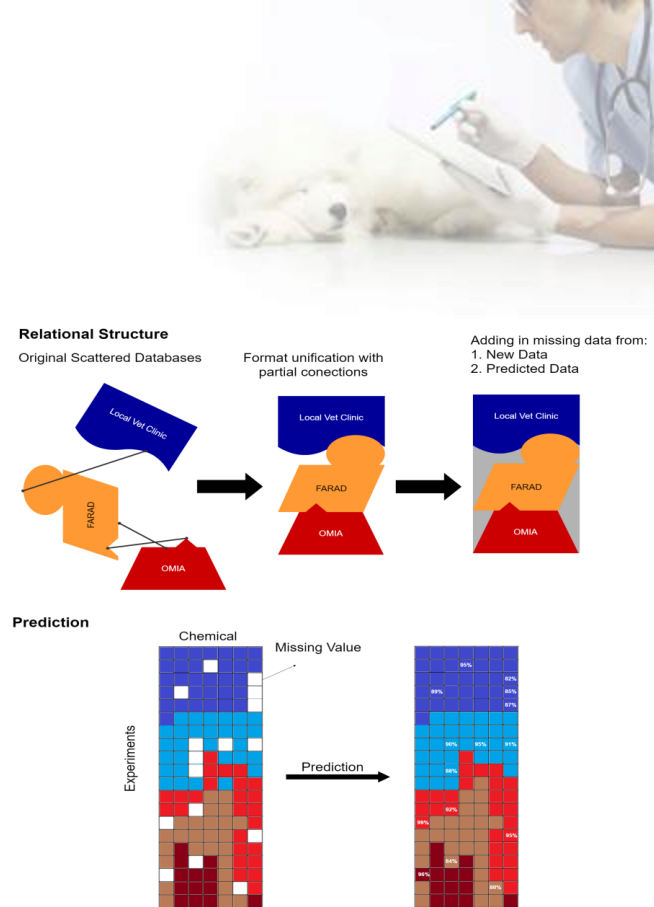
- **1Data** creates a *Structured Environment for Animal Data and Simulation* (SEADS), that combines disparate datasets, created for very different purposes, that then enables “Big Data” analytics to be applied to these “synthetic” datasets aggregated from real animal and human data.

1Data Databank



CONCLUSIONS

- Three decade experience with FARAD clearly shows the power of combining disparate databases into a single curated databank suite.
- 1Data presents the same opportunity for a much broader application where insights from animal health can be applied to human health (and vice versa).
- 1Data incorporates these disparate but related datasets with genomic and molecular biology resources to identify linkages not available through analysis of limited datasets.



CONCLUSION



- As 1Data grows, power of a SEADS environment dramatically increases.
- FARAD has already experienced power of 1Data by providing it with global drug databases and ADR data to help responders in real time environment. This also starts building sustainability of 1Data through revenue from FARAD project.
- Goal is to continue building SEADS with new data that both increases applicability of 1Data to One Health endpoints, but also diversifies revenue stream and allows for development of unique analytics.