

# Academic Perspectives on Sponsor/CRO Partnerships



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# Disclaimer

- The views expressed in this presentation are my own and do not represent the opinions, policies or practices of Kansas State University
- In the past 5 years, I have served as a paid consultant for Boehringer Ingelheim, Bayer Animal Health, Merck Animal Health, Norbrook Laboratories, Zoetis, and Midwest Veterinary Services

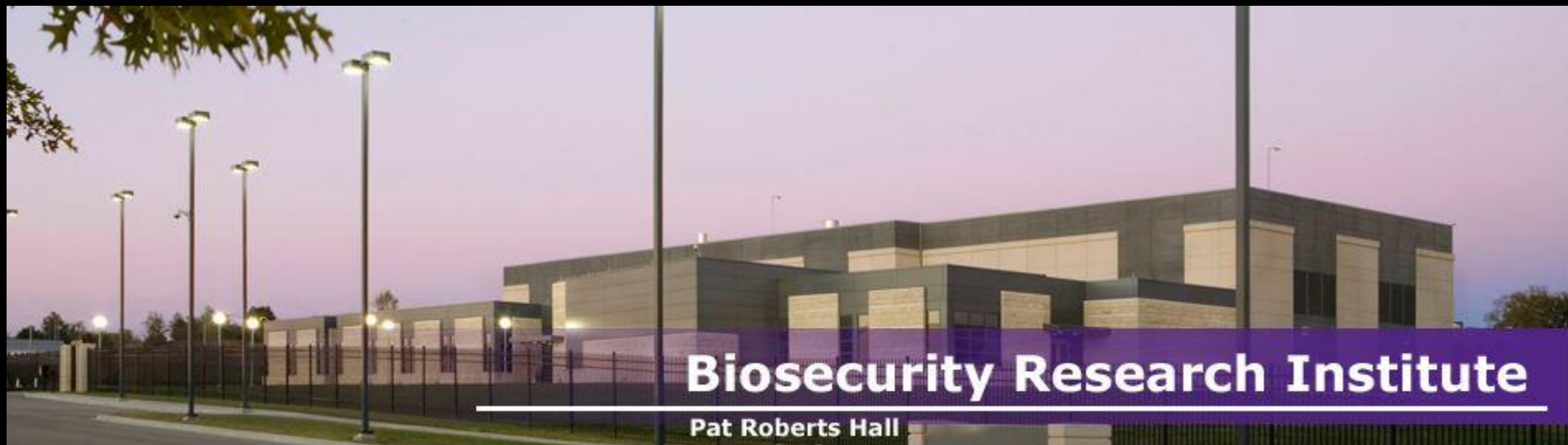
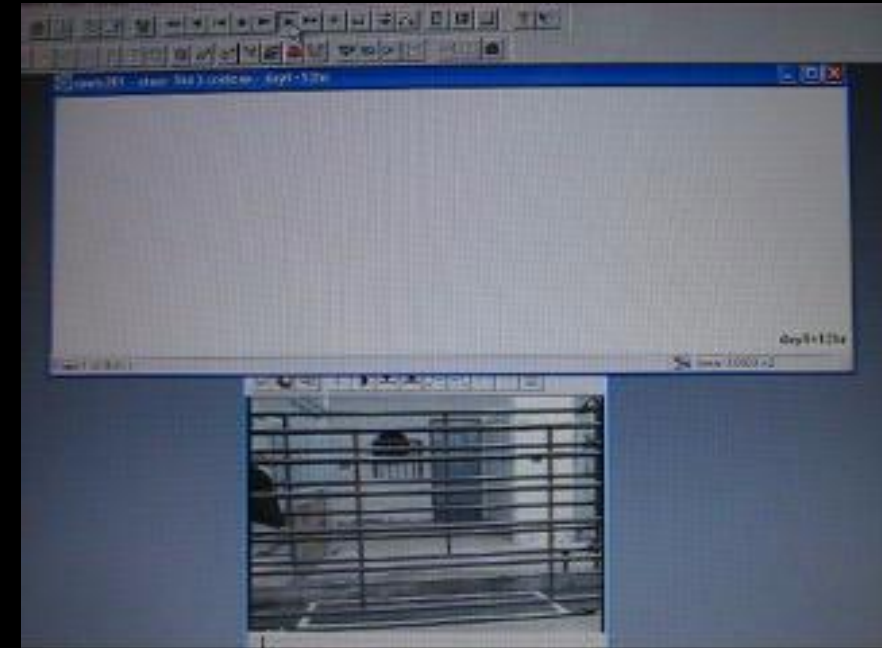
# My Background

- DVM, 4 years in private veterinary practice
- 2 years in Pharmaceutical R&D (Norbrook Laboratories, Newry, Northern Ireland)
- PhD, Board Certification in Clinical Pharmacology and Animal Welfare
- 5 years as a faculty member at K-State
- 5 years managing a fee-for-service lab at Iowa State University
- 2 years as Department Head at K-State

# What do universities offer CRO/ Sponsor Partnerships

- Intellectual Property
- Research models and test systems
- Highly specialized faculty with unique skills, experience and expertise
- Specialized facilities and equipment
- Objective assessment of new and existing technology (research perceived to be “unbiased”)

# What do universities offer CRO/ Sponsor Partnerships



# What do CRO/ Sponsors Partnerships offer Universities

- Source of funding
- Access to novel research materials and test compounds
- Support for graduate student training/ Externships
- Licensing opportunities for intellectual property
- Co-development opportunities, specifically experience with product approval, licensing and marketing
- Consulting opportunities for faculty to supplement their income

# 7 Pet Peeves of Universities working with Sponsors

1. One sided Confidential Disclosure Agreements (CDA's)
2. Governing law
3. GLP/GCP Studies → The prospect of an FDA Audit
4. Not including faculty salaries or graduate student tuition/ benefits on budgets
5. Itemized budgeting/ receipts → Having to give money back when the project is over
6. Corporate mergers and turnover of points of contact
7. Individual Faculty Conflict of Interest/ Conflict of Time

# 7 Pet Peeves of Sponsors working with Universities

1. “Indirect Costs” (AKA “Sponsored Research Overhead” “SRO”), “Facilities and Administration (F&A)”
2. Slow! (Contract Negotiations, IACUC approvals, IBC approvals, study execution and report preparation)
3. Quality Assurance (Compliance with GLP/ GCP)
4. Confidentiality (IACUC approval, student training, FOIA)
5. Requirements to publish research results regardless of outcome
6. Managing Intellectual Property
7. Data reproducibility



# Strategies for enhancing academic-sponsor partnerships

1. Master Services Agreements
2. Fee-for-service activities
3. CRO/ Third Party Collaborations

# 1. What is a Master Services Agreement?

A master service agreement, or MSA, is a contract reached between parties, in which the parties agree to most of the terms that will govern future transactions or future agreements.

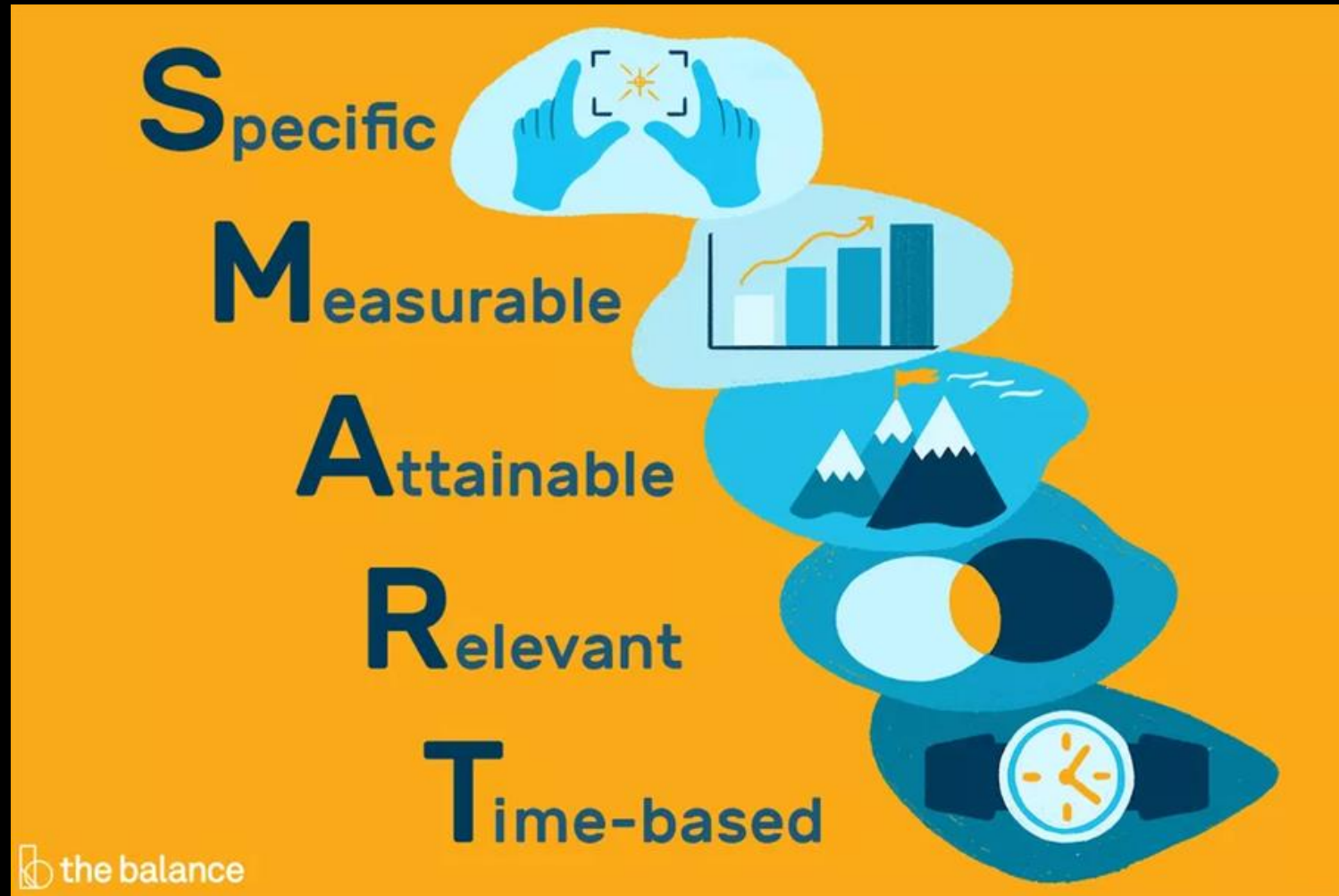
# Why set up MSAs with Universities?

- **Speed** up future contract negotiations
- Avoid negotiating rates and terms every time a new program of work is initiated
- Create flexibility for an overall research program instead of project by project
- Provides framework for managing IP/ Publications
- Facilitates long term research relationships

# What are the 4 components of a Master Services Agreement?

- Every responsible issue either party might face.
  - Budgeting, IACUC/IBC Approvals, Regulatory Considerations (USDA/FDA)
- What both parties will do together
  - Program of Study, Statement of Work, Goals and deliverables, Timeline
- What the other party must do (Sponsor)
  - Protocol Development, Provide test article, QA/QC, Payment schedule
- What your party must do (University)
  - Facilities & Test system, Study Execution, Data Collection/Analysis, Reporting

# MSA should also include SMART Goals



However, they can be tailored to the long term needs of both parties

A good MSA will frame the expectations for an overall program of work (single or multiple projects/ single or multiple researchers) instead of renegotiating terms and specifics on a project by project basis

# Advantages of MSAs

- SPEED!
- Once established, lawyers don't need to be involved
- If done well they are flexible, transparent and efficient
- Amenable to being written as a "template" that incorporates multiple studies over several years
- One MSA may impact more than one researcher or program of work at the university

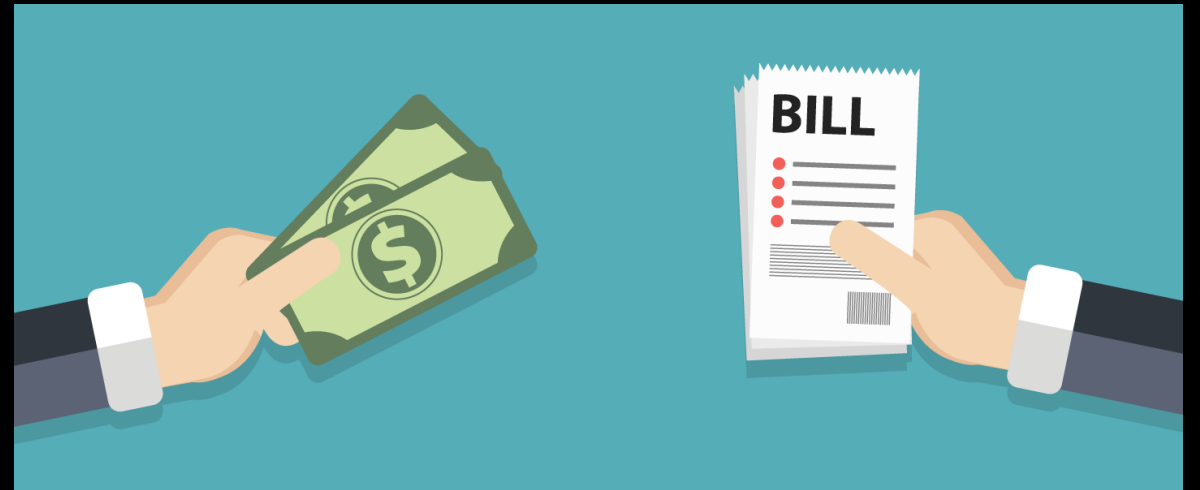
# Disadvantages of MSAs

- Work best when there is a Program of Work and not an individual study
- Corporate mergers/ turnover may be problematic
- Only provide efficiencies for long term relationships between parties (“A marriage not a date”)
- Can be inflexible depending on how they are written
- Dissolution of an MSA can impact multiple studies



## 2. What is Fee-for-service?

Fee-for-service (FFS) is a payment model where services are unbundled and paid for separately.



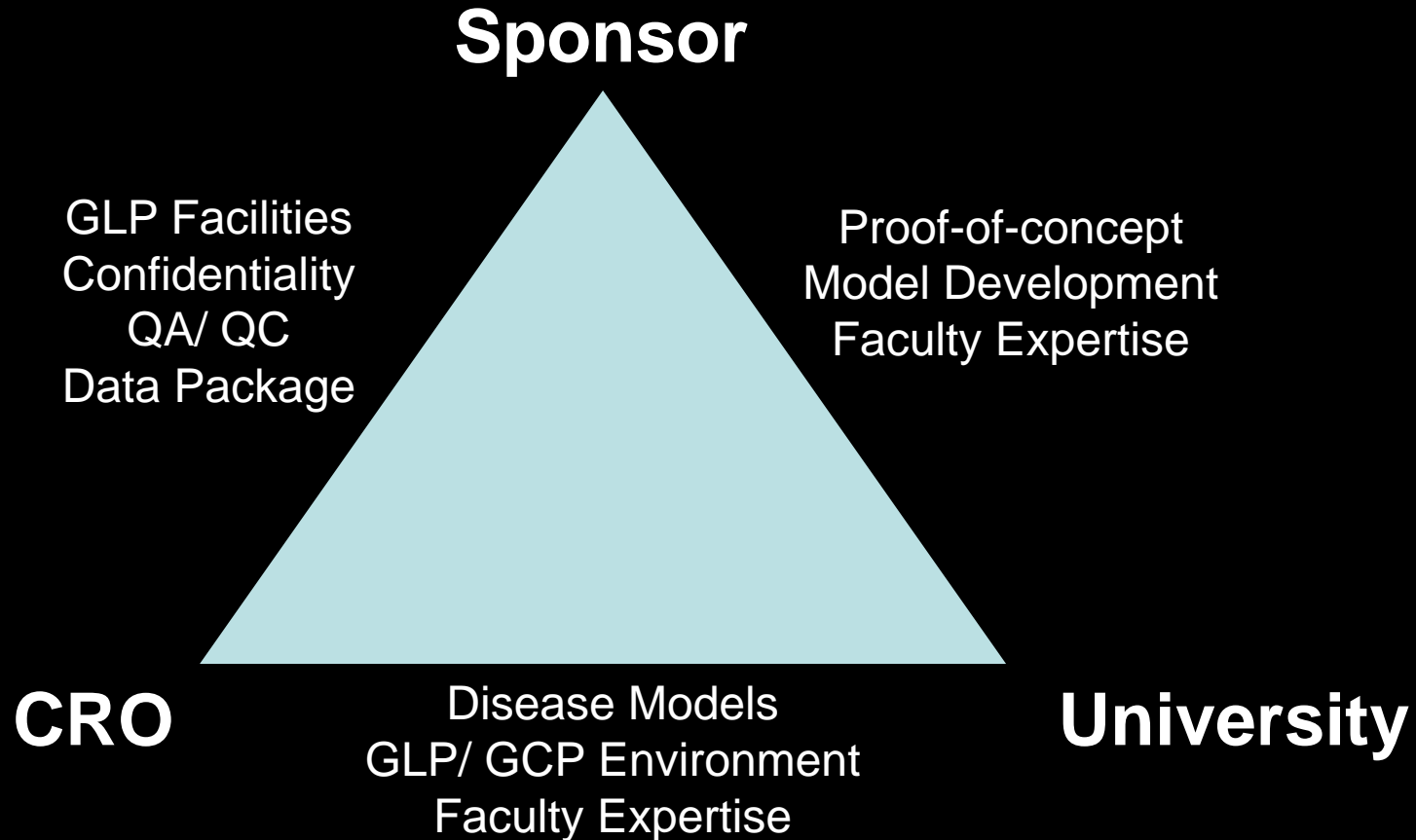
# Advantages of Fee-for-Service Agreements?

- Sponsor submits the samples and receives a spreadsheet with the results
- Fast → Once schedule of charges is established
- Transparency → Fee schedule is established upfront
- Results may be more reproducible
- University personnel masked to study details
- Typically no CDA, IACUC, IBC requirements
- No publication requirements or IP concerns

# Disadvantages of Fee-for-Service

- Tend to be Inflexible
  - Works best for assays, tests and itemized services
  - Challenging for scientific consultation and input
  - Quality Assurance issues (AAVLD vs. ISO vs. GLP)
  - Tests may not be customizable
  - May be challenging to change the way a test is conducted on a study-by-study basis (GLP/ GCP)

# 3. CRO/ Third Party Collaborations



# Advantages of CRO Collaborations?

- Translation of University developed disease models/ test systems into a GLP/ GCP environment for drug approval
- Reduced regulatory burden on Universities
- Reduces university investment on personnel and space
- Provides consulting opportunities for faculty
- May expedite pathway to regulatory approval

# Disadvantages of CRO Collaborations

- Potentially more paperwork to establish these relationships with 3 parties instead of 2 parties
- May increase the overall cost of the project
- Require more coordination
- Potentially have IP issues to resolve surrounding disease models

# Summary

- Sponsor/ CRO partnerships enhance scholarship and provide revenue for universities
- Project-by-project contract negotiation may not be an efficient way to structure these relationships and address the concerns of all parties involved
- MSA's, Fee-for-Service agreements and CRO collaborations may address these concerns and enhance these relationships.

# Questions?



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