

Technology Transfer: Animal Vaccines



**Office of Technology Transfer
Office of National Programs
Area Technology Transfer Office
Agricultural Research Service**

Topics to be covered:

- 1) Overview**
- 2) Priorities & Policies**
- 3) Partnerships & Agreements**
- 4) Patenting**
- 5) Licensing**
- 6) Summary**
- 7) Q&A**

Topics to be covered:

1) Overview

Mojdeh Bahar

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Animal Health Industry

- **U.S. Animal Health industry produced \$11.4 B of medicine**
- **\$10 B food-producing and companion animals in the U.S.**
- **Innovative**
- **Intellectual property driven**
- **Regulated by APHIS-USDA**

Veterinary Vaccines

- **23% of the global market for animal health products**
- **Vaccine development is a multidisciplinary endeavor-immunology, microbiology, protein chemistry, formulation or medicinal chemistry & molecular biology**
- **Vaccine Types: viral*, bacterial*, parasitic*, non-infectious diseases, fertility & production**

* Vaccines types that ARS conducts research on

Categories of Veterinary Vaccines

- **Companion Animals**
- **Livestock***
- **Wildlife***

* ARS conducts research in the following categories of vaccines: fish, swine, poultry, ruminants, horses, and wild animals that play a role in disease transmission.

Vaccine Platforms

- **Modified live**
- **Attenuated**
- **Inactivated**
- **Subunit**
- **Gene deleted**
- **Recombinant vectors**
- **DNA or RNA**
- **Synthetic**

Impact of Vaccines

- **Greatly impacts animal health by preventing diseases, and safeguarding animal welfare and production**
- **Significantly impacts public health through reduction in the use of medically important antibiotics and the control of zoonoses**

Things to Consider

- **Scientific challenges: purity, safety, efficacy (prevent clinical disease, transmission, cross-protection, onset, duration), potency, DIVA, stability, & safety**
- **R & D Timeline**
- **Production cost**
- **Intellectual property**
- **Regulatory affairs**
- **Policy considerations**
- **ROI-commercial viability**

Technology Transfer Principals

- Facilitate partnerships to allow adoption of research outcomes for **broad U.S. public benefit**
- Protect intellectual property only if it enhances adoption of research outcomes, not income generation
- Enhance U.S. economic development, global competition, & sustainable economic security

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2) Priorities & Policies Cyril Gay

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ARS Vaccine Priorities

- **Vaccines for animal production diseases**
- **Vaccines for foreign animal diseases**
- **Vaccines for emerging diseases**
- **Vaccines for zoonoses**
- **Vaccines as alternatives to antibiotics**
- **Vaccines for food safety pathogens**

ARS Guiding Principles

- ARS is a problem solving agency: why is a vaccine needed and what is the needed **product profile**?
- ARS conducts **vaccine discovery research**, but may also conduct **early development** studies to facilitate technology transfers
- ARS does not **develop** vaccines, which is beyond its core mission, capabilities, and available resources; therefore, all vaccine discovery research projects require a tactical plan to achieve a successful technology transfer to a commercial partner that has the ability and resources to implement a **full vaccine development plan** that will result in a product registration
- ARS may conduct **pivotal studies** in support of product registrations, if within the scope of a CRADA with a commercial partner

ARS Vaccine Research Policies

ARS is not a contract research organization (CRO) and therefore we do not test vaccines from other public or commercial institutions, unless:

- Advances ARS vaccine research programs**
- Needed to determine whether existing commercial vaccines are fit-for-purpose:**
 - A new improved vaccine is needed?**
 - Additional data needed to obtain product label claim that will benefit livestock producers?**
 - Emergency response to a disease outbreak?**

ARS Vaccine Research Policies

- **ARS vaccine research programs aim to address problems of high national priority**
- **Proof-of-concept efficacy and safety data in a relevant agricultural animal host is needed prior to submitting an invention disclosure**
- **A technology transfer strategy must be identified: a) exclusive license, b) non-exclusive license, c) no license**
- **Exclusive license strategies require a technology transfer tactical plan.**

Technology Transfer Tactical Plan

- **Developed with ARS scientists, TTC, ONP, and OTT**
- **Goal is to achieve the full potential impact of the research**
- **ARS invention or contributions from collaborators?**
- **Patent landscape by OTT patent advisor**
- **Protecting intellectual property (IP) plan**
 - **File provisional patent application?**
 - **Hold patent application?**
 - **How many patents are needed?**
 - **Are additional data and IP needed?**
- **Identification of criteria for selecting commercial partner**
- **Identification of commercial partners that meet the criteria**
- **Process for selecting commercial partner and agreement**

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Rob Griesbach

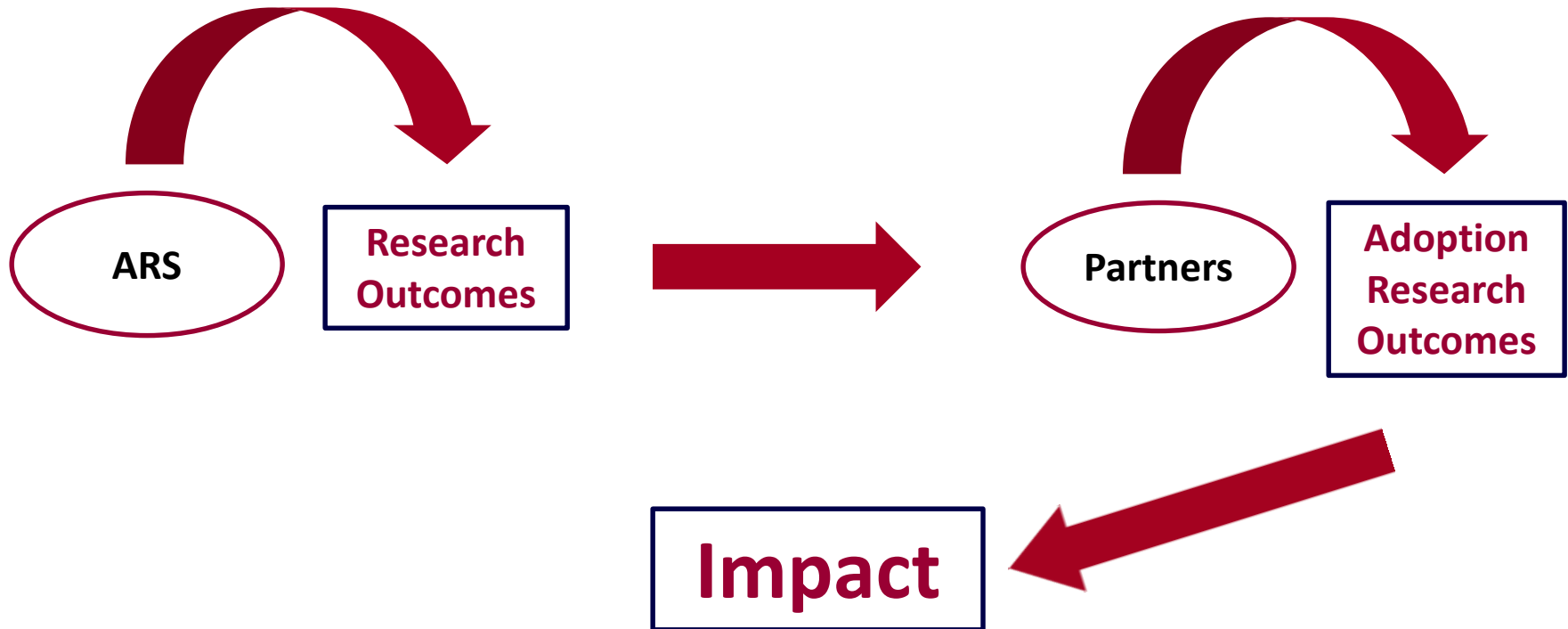
4) Patenting

5) Licensing

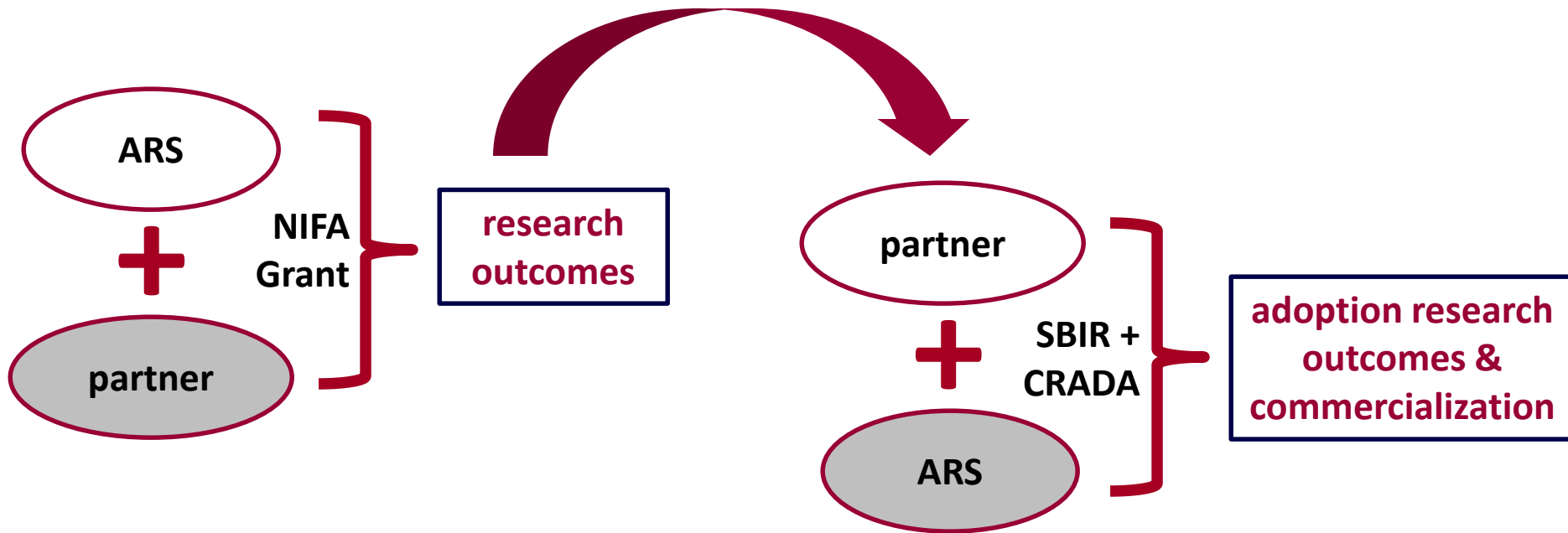
6) Summary

7) Q&A

Partners play key role



Types of Partnerships

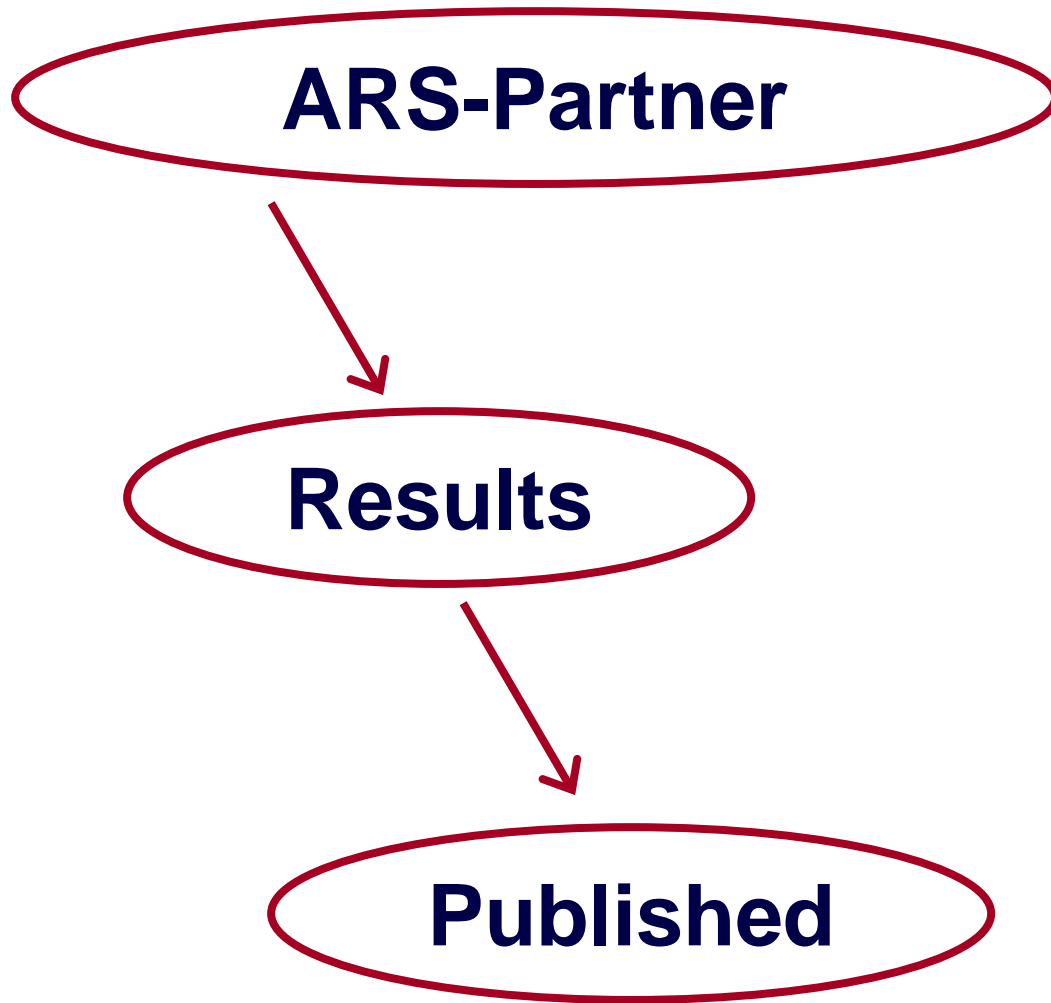


Selecting a Partner

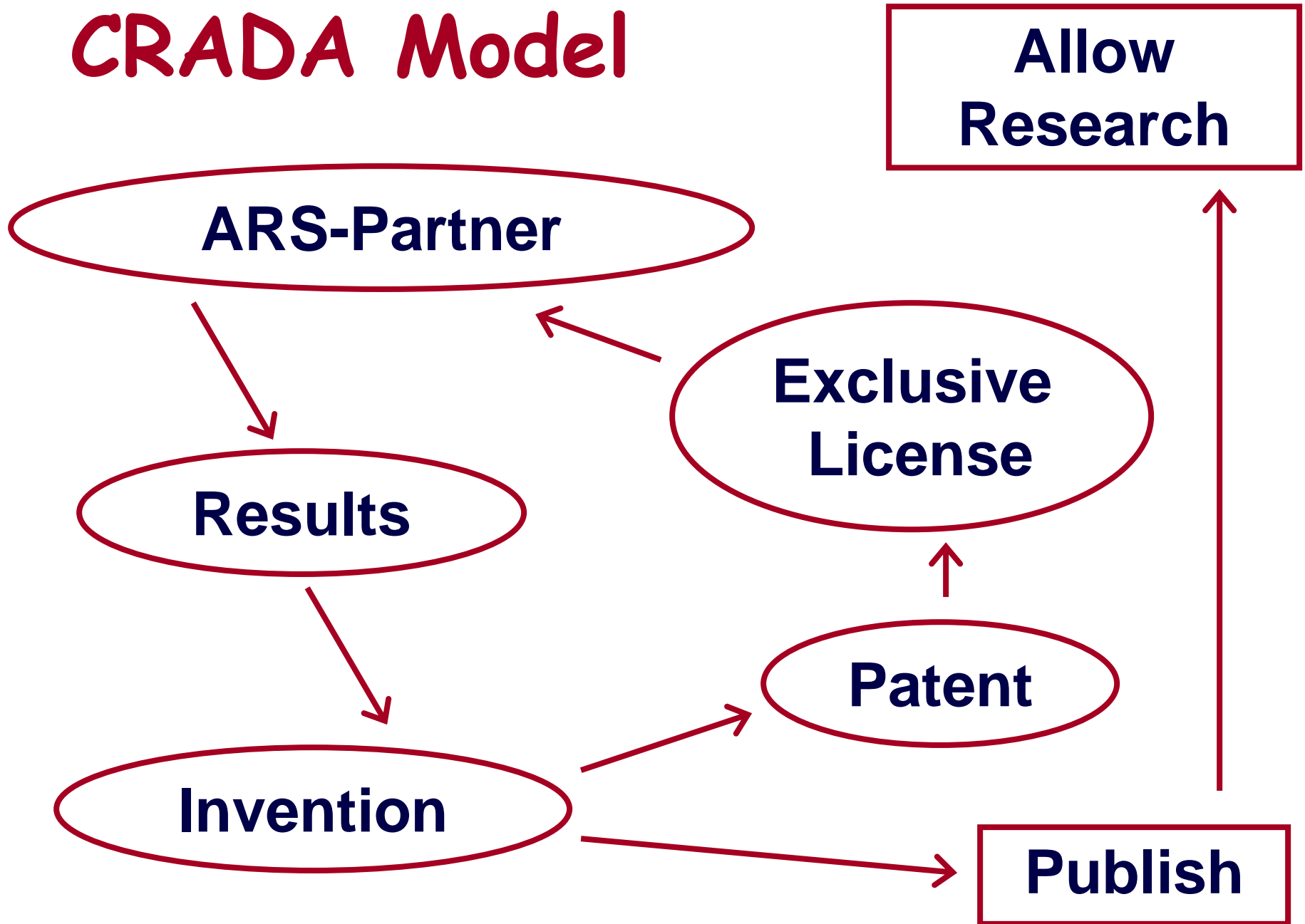
What complementary assets are needed?

- **Could another ARS location(s) or scientist(s) provide the necessary expertise, materials, or facilities?**
- **Does the partner provide unique resources not otherwise available?**
 - ✓ **Technical expertise**
 - ✓ **Specialized equipment**
 - ✓ **Unique facilities**
 - ✓ **Manufacturing expertise**
 - ✓ **Registration experience**
 - ✓ **Fiscal resources**

TFCA Model



CRADA Model



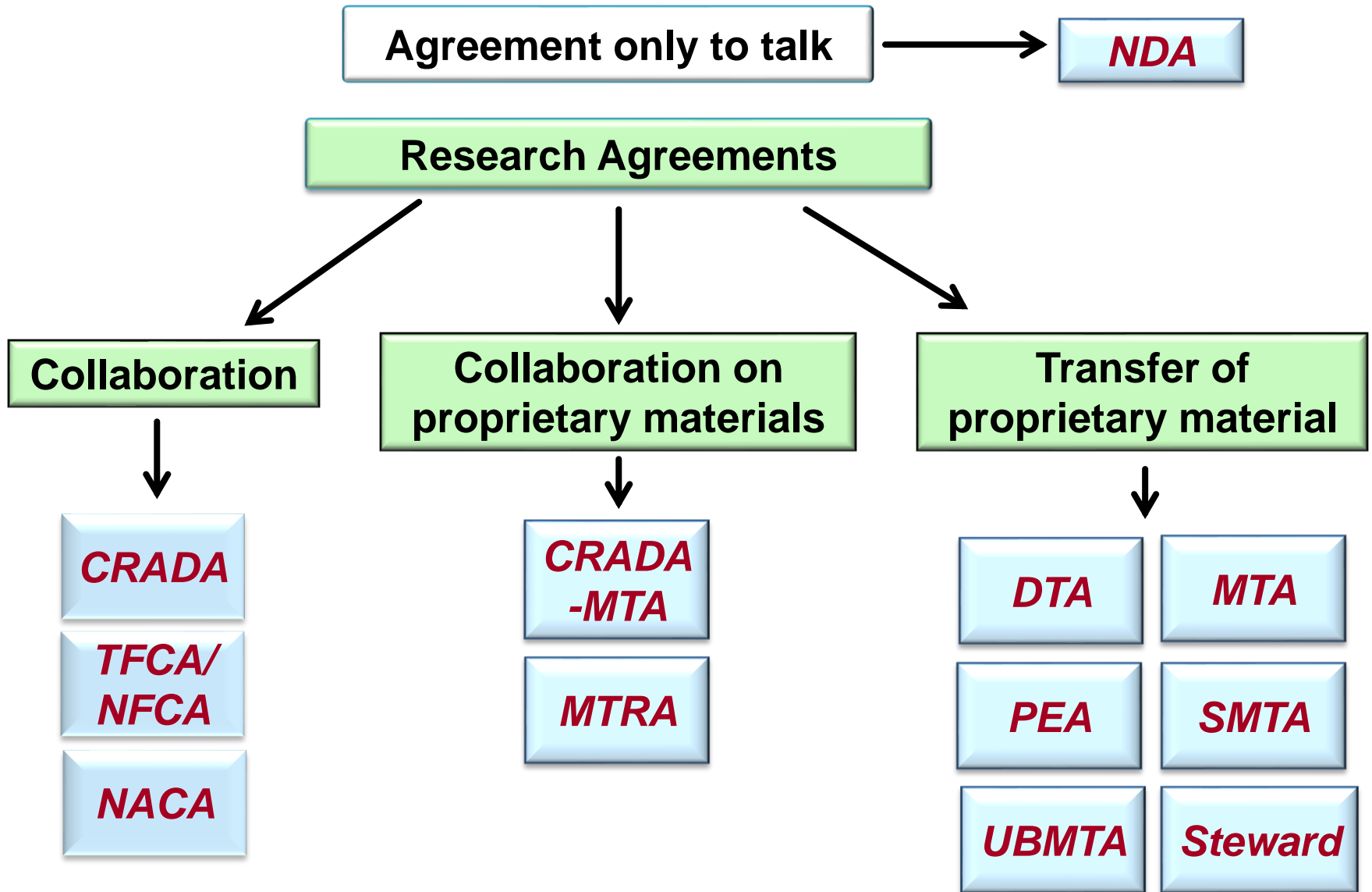
CRADA

- ✓ **One agreement with the same SOW**
- ✓ **IP protection & confidentiality provisions**
- ✓ **Right to negotiate exclusive license**

TFCA

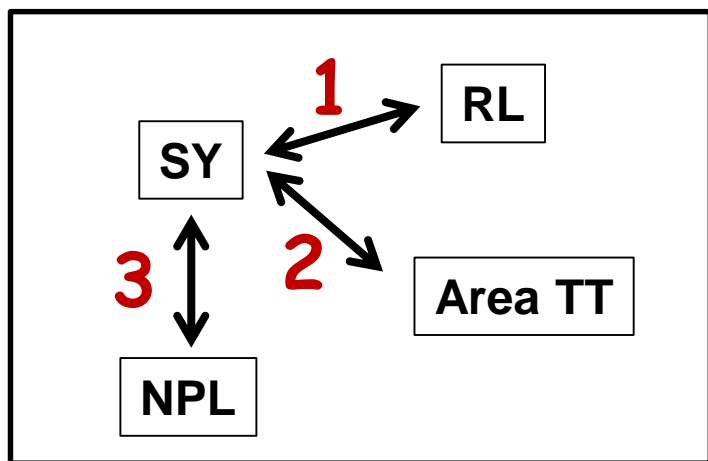
- ✓ **Multiple agreements possible with the same SOW**
- ✓ **No IP protection & no confidentiality provisions**
- ✓ **No right to negotiate exclusive license**

Agreement = SOW + Legal

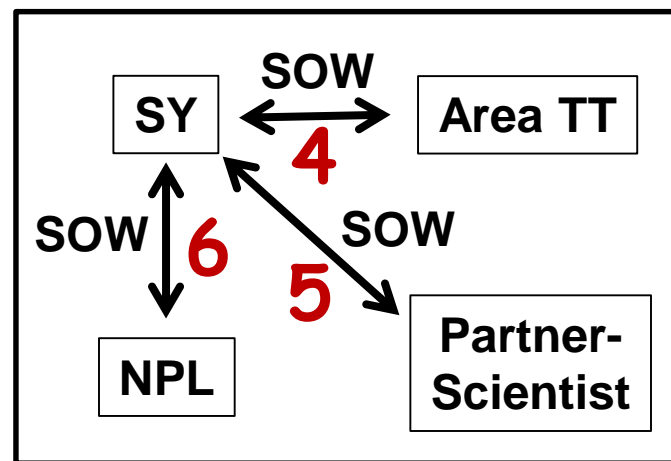


CRADA-MTRA Review & Approval

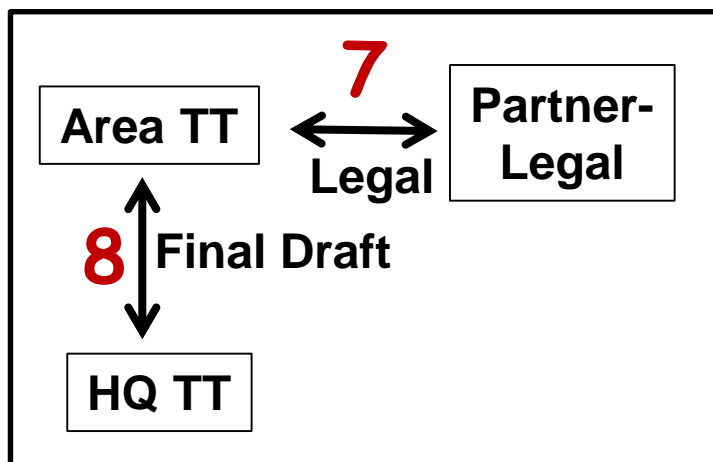
Phase 1



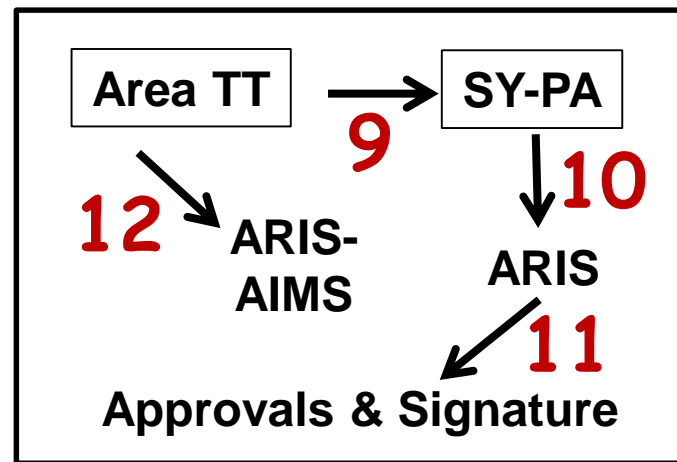
Phase 2



Phase 3

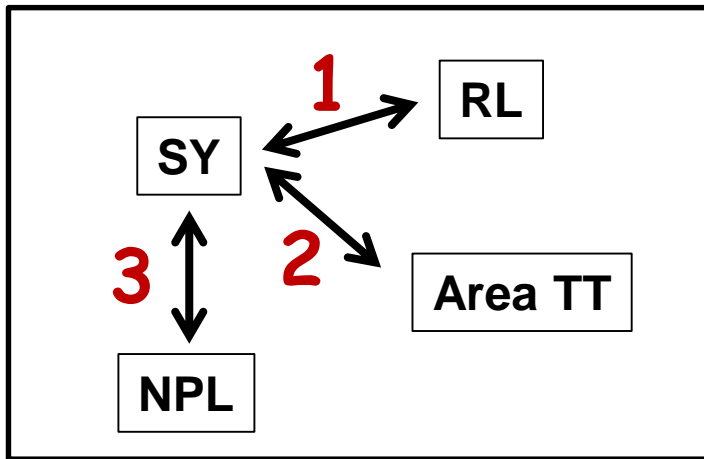


Phase 4

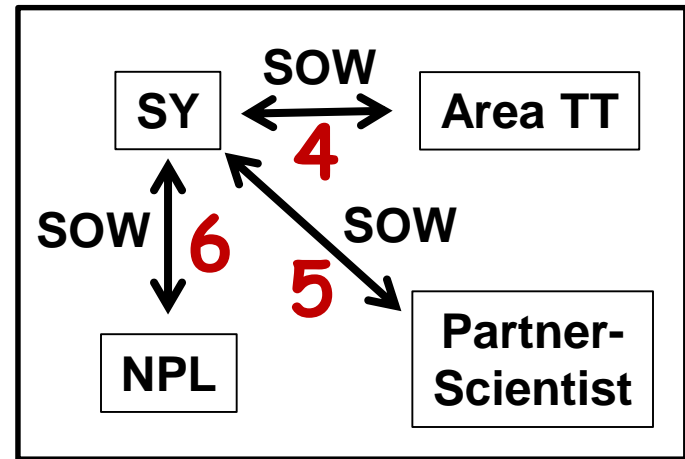


All You Need to Know

Phase 1



Phase 2



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4) Patenting

Gail Poulos

- 1) Licensing**
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Utility Patents

Right to exclude others from making, using, selling, offering for sale, and importing the patented technology in the granting territory for 20 years after the effective filing date

Inventorship vs. Authorship

Inventorship

- Cannot be decided by the inventors- legal determination
- Based on contribution to overall “conception of invention”
- Wrong inventorship may have serious consequences for the patent owner
- Inventorship is based on the claims in a patent application

Authorship

- Can be decided by the inventors
- Based on contributions in designing/performing experiments or in writing the resulting manuscripts
- Authorship can be based on any part of a scientific paper

ARS Patent Policy

- Pursues patent protection when it facilitates technology transfer
- Research 'tools' are usually not patented
- Generally allows non-commercial research without a license
- Research outcomes belong to ARS, not the scientist (scientists assign rights to ARS)
- ARS, not the scientist, decides whether or not to file for a patent
- **ARS patent and publishing policies are not incompatible, consult with a Patent Advisor before publishing.**

Reasons for Patenting Vaccines

- **Facilitates technology transfer:**
 - ✓ Incentive for investments by private sector*
 - ✓ Increase research impact
- **Expands use to foreign countries**
- **Enhances U.S. economic development, global competition, & sustainable economic security**

*Vaccines require regulatory approval, a process that is very expensive. Businesses need the promise of market exclusivity to justify investment.

Considerations for Patentability

- What aspect(s) of the vaccine are **new and/or different**?
- Are there **nucleic acid/protein modifications**?
 - Are some of the **antigens/epitopes/serotypes** known to work? (polyvalent)
- Are **adjuvants** needed?
- Does the **form** of the vaccine, or **route** of administration affect functionality?
 - Examples:
 - Nanoparticles vs. protein in saline
 - Live vs. killed
 - Co-expression / co-application with immune stimulator vs. not
 - Parenteral, intranasal, or oral
- What are the **production** methods or any **efficiencies** gained (e.g. faster, better, cheaper, more efficient, less cross reactivity) ?

Animal Studies

- **To support claims for patent protection, *in vivo* data is critically important**
 - ✓ **Animal studies vs. cell line studies**
 - ✓ **Target animal vs. surrogate animal**
- **A major factor considered in seeking patent protection is the presence/absence of animal data demonstrating effectiveness**

Ownership of Starting Material

- **Did you acquire any component of the proposed vaccine from others?**
 - ✓ **Vectors, cell lines, strains, non-public genetic sequences**
- **Does an agreement exist regarding the transfer of a component?**
 - ✓ **Written agreement (MTA, MTRA, CRADA, purchase agreement, etc.)**
 - ✓ **Oral agreement**
 - ✓ **No agreement**
- **If an agreement exists, ...**
 - ✓ **Did it exist prior to using the material/component?**
 - ✓ **Does it permit vaccine development and/or commercialization?**

Intellectual Property Rights Outside U.S.

- **Geographic distribution of the pathogen**
- **Corporate partners often interested in foreign market**
 - ✓ **Transboundary/Global pathogens**
 - ✓ **Diseases not prevalent in the U.S.**
- **Publishing before filing a patent application can destroy I.P. rights**

DIVA Vaccines

- **Ownership:**
 - ✓ If as the owner of a vaccine you have genetically modified the pathogens to differentiate infected from vaccinated animals (DIVA), then the vaccine has dominating rights and licensing potential can be limited.
- **New Features:**
 - ✓ Have you developed the specific antigenic/genetic changes that allow differentiation?
 - ✓ Have you developed the companion diagnostic test to differentiate infected from vaccinated animals
 - ✓ Patent claims may be limited to the differentiation methodology(ies) actually performed and reported in an application.
- **Animal Studies:**
 - ✓ Without data showing you can differentiate infected from vaccinated animals:
 - Approval by regulatory agency is not likely
 - A patent office is likely to reject claims for lack of support
- **Global Rights:**
 - ✓ Important to countries to establish and maintain “disease-free” status

LABORATORY NOTEBOOK

- **Good Laboratory Notebook Practice Training Slides:**
<https://www.ars.usda.gov/office-of-technology-transfer/ott-training-1/>
- **ARS Laboratory Notebooks are bound notebooks USE OFFICIAL ARS Laboratory Notebook (ARS FORM 1)**
- **Electronic Laboratory Notebook**

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Brian Nakanishi

- 1) Summary**
- 2) Q&A**

Please Memorize

- **Goal is technology transfer, NOT revenue generation**
- **Very important to involve TTC, NPL, and PA as early as possible**
- **Increases likelihood of licensing technology to a commercial partner**

Conflict of Interest

- While technical discussions with potential licensees are okay, scientists must **NOT** participate in business discussions
- Refer potential licensees to the licensing section

Key Points

- **Commercial partner is necessary to achieve technology transfer**
- **An exclusive license strategy may be necessary due to high cost of vaccine development**
- **International patent protection may be needed**
- **Vaccine must be commercially viable**

Timing is Critical

- **Determining the right time to bring in a commercial partner**
- **Issues to consider**
 - ✓ **Criteria for selecting a commercial partner**
 - ✓ **FR Notice**
 - ✓ **Co-ownership**
 - ✓ **Small vs Large commercial partner**
 - ✓ **Risk**
- **Consult with NPL, TTC, and OTT as early as possible**

Intersection of CRADA & Licensing

- **This is most important when there is background IP, i.e., IP that was created prior to the start of the CRADA**
- **CRADAs are prospective- they capture the inventions that may be developed under the SOW**
- **Licenses are retrospective-they are concerned with previously developed IP**
- **Please note that a CRADA does not provide a license/option to license to the background IP**

Regulatory Framework

- **USDA – Center for Veterinary Biologics (CVB) in the Animal and Plant Health Inspection Service (APHIS)**
- **Virus-Serum-Toxin Act of 1913, as Amended in 1985**
 - ✓ **Permit required to ship experimental biologics from laboratory (9 CFR 103.3)**
 - ✓ **To manufacture and sell veterinary biologics, animal health companies need establishment license and product license from CVB**
 - ✓ **Review process can take 3 to 5 years**
- **FDA – Center for Veterinary Medicine (CVM)**
 - ✓ **Ensure animal drugs are safe and effective and can be consistently manufactured to approved specifications**
 - ✓ **Review process can take 7 to 10 years**

Timeline of Licensing Process

- **License Application**
 - ~ 1 month to be complete and sufficient.
- **Federal Register Notice**
 - ~ 2 to 3 months to process and receive approvals.
 - 1 month for publication.
 - Only for exclusive license agreements.
 - Does not apply to CRADA Subject Inventions.
- **Draft License Agreement**
 - ~ 2 to 3 weeks to draft and review internally.
 - ~ 1 week to revise based on comments.
- **Negotiation/Execution**
 - Depends on legal review by potential licensee.
 - ~ 1 to 3 months.

Licensing Revenue Distribution

- **Co-inventor's Institute/Company**
- **ARS**
 - ✓ **Inventor(s) incentive award**
 - ✓ **OTT operating expenses**
 - ✓ **Innovation Fund**

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General Technology Transfer Presentations

 **Technology Transfer: Introduction** (Web Based ARS-OTT-Insider-Threat-Mod1)
Online Course ✔ Already Assigned


This training will focus on the basics of technology transfer, on how and when to engage with techno [more](#)

☆☆☆☆☆ Not yet rated
Free

 **Technology Transfer: Licensing** (Web Based ARS-OTT-Insider-Threat-Mod4)
Online Course


This training will focus on the basics of technology transfer, on how and when to engage with techno [more](#)

☆☆☆☆☆ Not yet rated
Free

 **Technology Transfer: Partnerships and Agreements** (Web Based ARS-OTT-Insider-Threat-Mod2)
Online Course

This training will focus on the basics of technology transfer, on how and when to engage with techno [more](#)

☆☆☆☆☆ Not yet rated
Free

 **Technology Transfer: Patenting** (Web Based ARS-OTT-Insider-Threat-Mod3)



Technology Transfer: Introduction (Web Based ARS-OTT-Insider-Threat-Mod1)

Online Course

This training will focus on the basics of technology transfer, on how to engage with techno [more](#)

☆☆☆☆☆ Not yet rated

Free



Technology Transfer: Licensing (Web Based ARS-OTT-Insider-Threat-Mod4)

Online Course

This training will focus on the basics of technology transfer, on how and when to engage with techno [more](#)

☆☆☆☆☆ Not yet rated

Free



Technology Transfer: Partnerships and Agreements (Web Based ARS-OTT-Insider-Threat-Mod2)

Online Course

This training will focus on the basics of technology transfer, on how and when to engage with techno [more](#)

☆☆☆☆☆ Not yet rated

Free



Technology Transfer: Patenting (Web Based ARS-OTT-Insider-Threat-Mod3)



U.S. Department of Agriculture
Agricultural Research Service



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- **Axon Help**
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- Search for People within Axon
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Science Links



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ARS Calendar

Axon > Office of Technology Transfer

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Office of Technology Transfer



OTT Intranet

The Office of Technology Transfer (OTT) is responsible for ARS' technology transfer program and is delegated the authority to administer the patent and licensing program for all intramural research conducted by USDA. The OTT helps move ARS research discoveries to the marketplace.

Innovation Fund Announcement

Dr. Jacobs-Young announced the establishment of the ARS Innovation Fund on June 8, 2016. The purpose of the fund is to enhance the commercial potential of an agricultural solution currently under development at ARS, with the ultimate aim being to facilitate the adoption of ARS's research by industry, academia and other stakeholders. The ARS Office of Technology Transfer (OTT) is at the helm as we undertake a pilot of the fund this year.



If you need up to \$25,000 to take your research to the next level, consider submitting an application for the innovation fund. I have attached the application for your ease of reference, but it is also here on-line. Applications are due to OTT (Melissa.Repoza@ars.usda.gov) no later than Friday June 24, 2016. The applications will be reviewed and some funded. In this first round, \$250,000 is available, with another round following later this fiscal year.

Quick Links

- OTT on the ARS Website

OTT Training:

- ARS Export Control.pptx
- T2_Introduction.pdf
- T2_Agreements.pdf
- T2_Licensing.pdf
- T2_Patenting.pdf
- Plant_Release_Procedure.pptx

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Related Topics

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OTT Training (1)



Training

Click on the training presentation or document that you would like to view or print below:

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- [Tech Transfer: Agreements](#)
- [Tech Transfer: ARP Network](#)
- [Tech Transfer: Licensing](#)
- [Tech Transfer: Patenting](#)
- [ARS T2 Working Group Report](#)
- [Standard Material Transfer Agreement \(SMTA\)](#)
- [The America Invents Act \(AIA\)](#)
- [Directions for Submitting Invention Disclosure- New Invention Disclosure](#)
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Lab Notebooks

- [Lab Notebook Supply Order Form](#)
- [Good Laboratory Notebook Practices \(Color\)](#)
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“Deal Breakers” in Vaccine Research



Question No. 1:

I developed a vaccine in 2006. I entered into a CRADA with a Company XYZ in 2010. I have told XYZ that as my CRADA partner XYZ has an exclusive option to the vaccine that I developed in 2006.

Deal or No Deal?



Question No. 2:

I have received a call from one of my collaborators, she informed me that her employer filed a patent application and wants my signature assigning my rights to her employer.

Deal or No Deal?



Question No. 3:

I'd like to send some of the biological material (the active component in my vaccine) I have developed to a collaborator. Even though I know her very well and trust her, I still need an agreement.

Deal or No Deal?



Question No. 4:

I understand that I need data to support my assertions in an invention disclosure. I want to be sure that I have all the data I need for my vaccine to be approved before I submit an invention disclosure.

Deal or No Deal?



Question No. 5:

Even though my co-inventor's university is filing a patent, I still need to submit an invention disclosure into ARIS.

Deal or No Deal?



Question No. 6:

I have an active component for a vaccine against a deadly animal disease. Delivering this immunogenic composition requires a viral vector. I can use any vector whether or not it is patented.

Deal or No Deal?



Question No. 7

I made an improvement to an existing vaccine. I need to file an invention disclosure.

Deal or No Deal?



Question no. 8

I only made an incremental improvement to my patented vaccine. I do not need to file an invention disclosure.

Deal or No Deal?



QUESTIONS



**Tech Transfer is
a Team Effort**

**OTT, TTC-TAA, & ONP
are here to help**