

# Preparedness, Pandemics, and Program Management: Embracing Serendipity in a Scientific Career

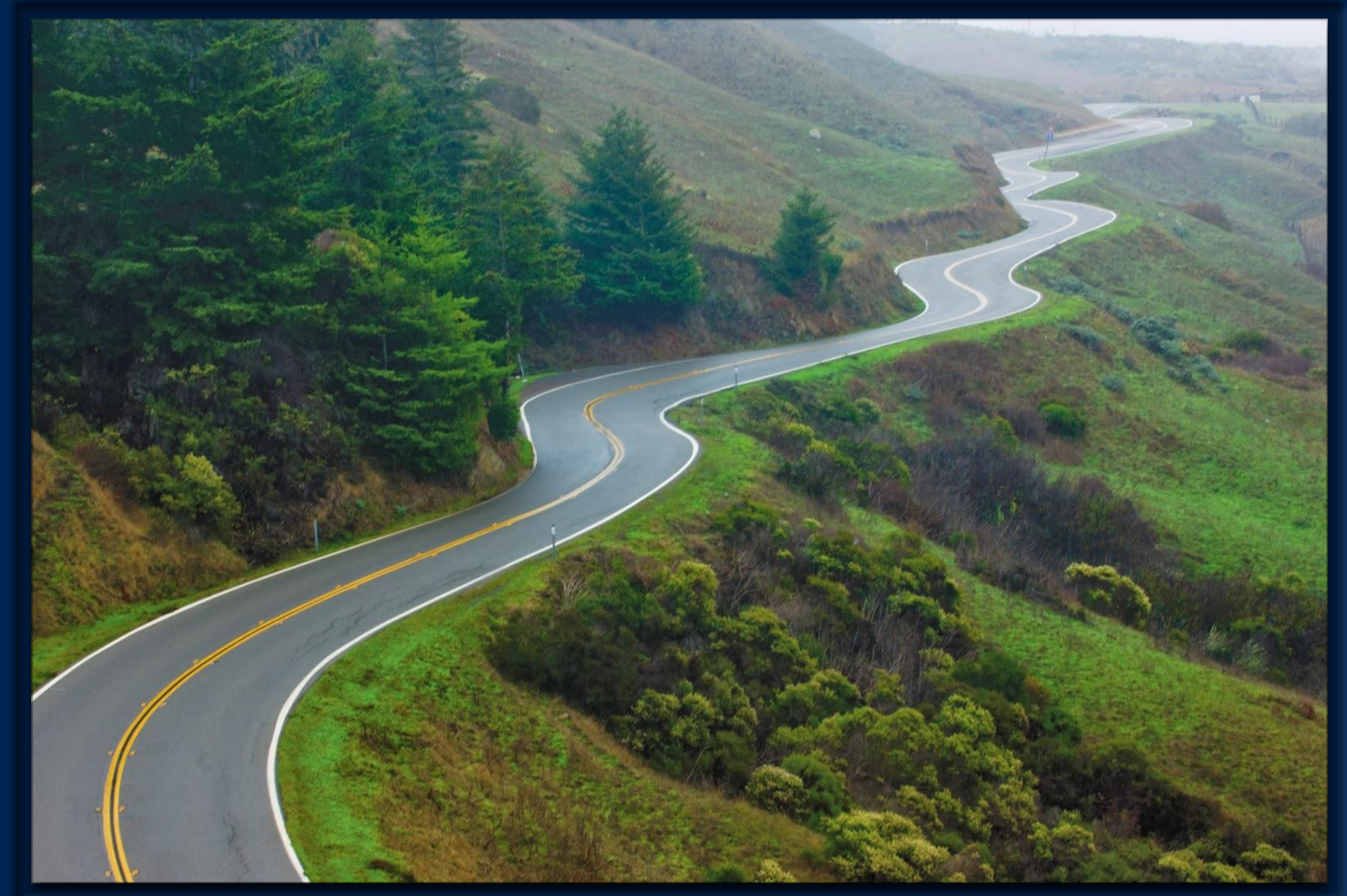
Matthew Lawlor, PhD

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# Agenda

- ◉ **Three career experiences**
  - ◉ Science policy
  - ◉ Contract management
  - ◉ Program management
- ◉ **For each career**
  - ◉ My experience
  - ◉ Sample work product
  - ◉ Opportunities

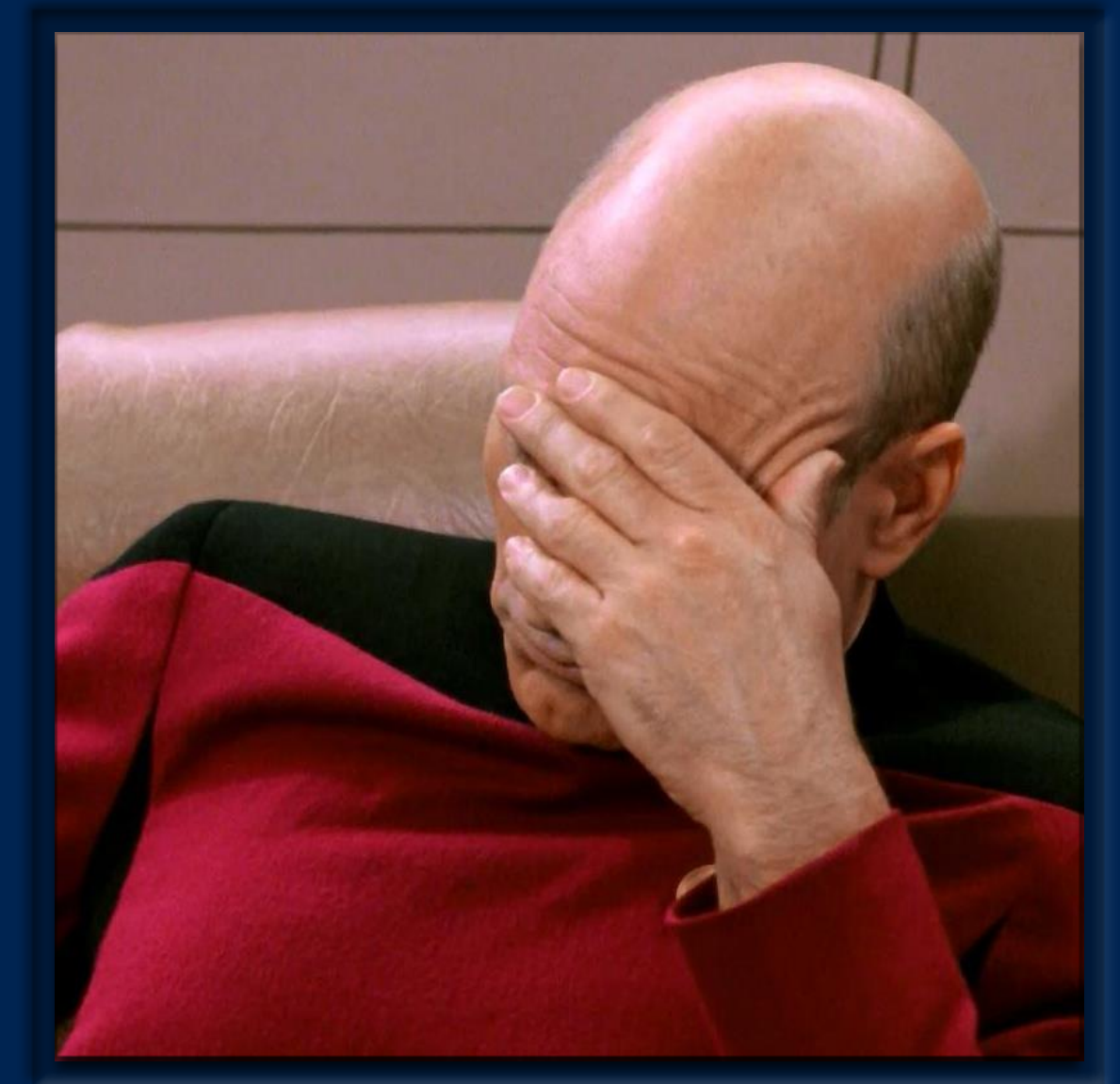




# Science Policy

## *My Start*

- ◉ Began researching science policy opportunities about halfway through graduate school
  - ◉ Lots of dead-ends
- ◉ Two years before graduation, applied to three different fellowship programs
  - ◉ No awards
- ◉ Prior to graduating, re-applied to all three programs
  - ◉ Awarded Presidential Management Fellowship



# Science Policy

## *My Experience*

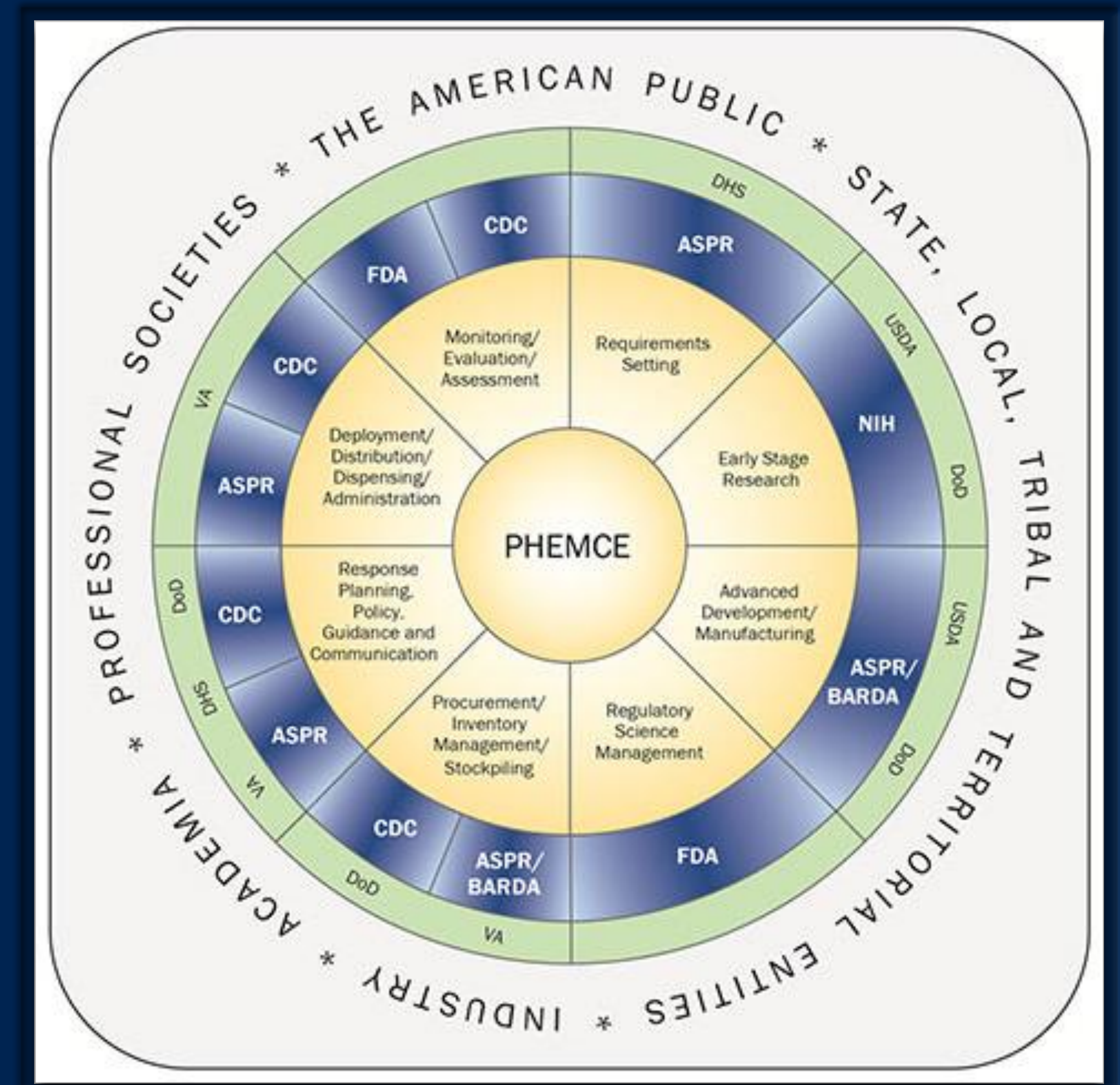
- ◉ Presidential Management Fellow for 2 years at the US Department of Health and Human Services in the Office of the Assistant Secretary for Preparedness and Response
- ◉ Establishing medical countermeasure requirements and policies to prepare for intentional biological threats [anthrax, smallpox, etc.]
- ◉ Detailed to CDC to work on first National Biosurveillance Strategy for Human Health
- ◉ Positions: PMF; Program Analyst; Biological Threats Branch Chief





# HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- Decision-making body to coordinate investments and activities across multiple departments and agencies
- Top-level body includes CDC Director, NIH Director and ASPR
- Next-level group is comprised of Deputy Directors
- Working groups include subject matter experts to review scientific data and make recommendations
  - e.g., optimal vaccine characteristics





# Science Policy

## *Sample Work Product*

### How much anthrax vaccine should we stockpile?

- ◉ Define the threat
  - ◉ Material threat determination by the Department of Homeland Security
  - ◉ Medical consequence modeling to determine potential number of illnesses and deaths during an event
- ◉ Evaluate the product landscape
  - ◉ Current products, manufacturing capacity, and shelf life
  - ◉ Next generation products and development timeline
- ◉ Prioritize across biodefense portfolio





# HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats (April 2007)

- Result of months of deliberations and negotiations
- First time that the federal government communicated priorities for CBRN medical countermeasures
- Downstream impacts on priorities for federal agencies and product developers

BIOLOGICAL THREATS	Near-Term (FY 2007-08)		Mid-Term (FY 2009-13)	
	Funding Source	Funding Level <sup>1</sup>	Funding Source	Funding Level <sup>1,2</sup>
Diagnostics			<b>SRF</b>	<b>X</b>
Broad spectrum antibiotic(s)	<b>DSNS</b>	<b>X</b>	<b>DSNS, SRF</b>	<b>X, XX</b>
Anthrax antitoxin(s)			<b>SRF</b>	<b>XX</b>
Anthrax vaccine(s)	<b>SRF</b>	<b>XX</b>		
Medical Countermeasure(s) for Filoviruses			<b>SRF</b>	<b>XX</b>
Smallpox antiviral(s)			<b>SRF</b>	<b>X</b>
Smallpox vaccine	<b>SRF</b>	<b>XX</b>		
RADIOLOGICAL and NUCLEAR THREATS	Near-Term (FY 2007-08)		Mid-Term (FY 2009-13)	
	Funding Source	Funding Level <sup>1</sup>	Funding Source	Funding Level <sup>1,2</sup>
Medical Countermeasure(s) for ARS/DEARE	<b>SRF</b>	<b>XX</b>	<b>SRF</b>	<b>XX</b>
Biodosimetry, Bioassay			<b>SRF<sup>‡</sup></b>	<b>X</b>
Radionuclide-specific agent(s)			<b>SRF</b>	<b>X</b>
CHEMICAL THREATS	Near-Term (FY 2007-08)		Mid-Term (FY 2009-13)	
	Funding Source	Funding Level <sup>1</sup>	Funding Source	Funding Level <sup>1,2</sup>
Enterprise CHEMPACKs			<b>DSNS</b>	<b>XX</b>



# Science Policy *Opportunities*

	Pros	Cons
◉ National Academies: Christine Mirzayan Science & Technology Policy Graduate Fellowship Program	Good crash course Connection to National Academies	~3 months No connection to future employment
◉ AAAS: Science & Technology Policy Fellowships	Prestigious Executive branch and Congressional committee positions Excellent network 1 year with option for a second	No connection to future employment
◉ Presidential Management Fellowships	Strong reputation Wide variety of executive branch positions Good network Includes one rotation 2 years Converts into permanent federal position	Mostly non-science positions
◉ Non-profits and advocacy organizations	Less competitive than fellowship programs Quicker to start	Opportunities are difficult to find, and are likely entry-level



# Contract Management

## *My Experience*

- ◉ After 4 years in policy, interested more in “science” than “policy”
- ◉ Biomedical Advanced Research and Development Authority (BARDA)
  - ◉ Responsible for developing vaccines, therapeutics, and diagnostics from Phase 2 clinical trials through licensure and acquisition
  - ◉ Targeted pathogens include CBRN threats, pandemic influenza, and emerging infectious diseases
- ◉ Position: Project Officer, Influenza and Emerging Diseases Division
  - ◉ Oversaw \$179M development contract for recombinant influenza vaccine
  - ◉ Project Officer on first Broad Agency Announcement for Influenza Medical Countermeasures
  - ◉ Served on biosurveillance task force during 2009 H1N1 pandemic





# Project Officer

## *A Brief Definition*

- ◉ Once contract is awarded, provides technical oversight of contractor progress towards all deliverables
- ◉ Partners with Contracting Officer
  - ◉ Responsible for oversight of all financial aspects of the contract
- ◉ Serves as lead for team of subject-matter experts reviewing progress
- ◉ Reviews monthly technical reports and chairs quarterly site visits

***BARDA Subject-Matter  
Experts***

*Manufacturing*

*Process and Analytical*

*Preclinical*

*Clinical*

*Regulatory*

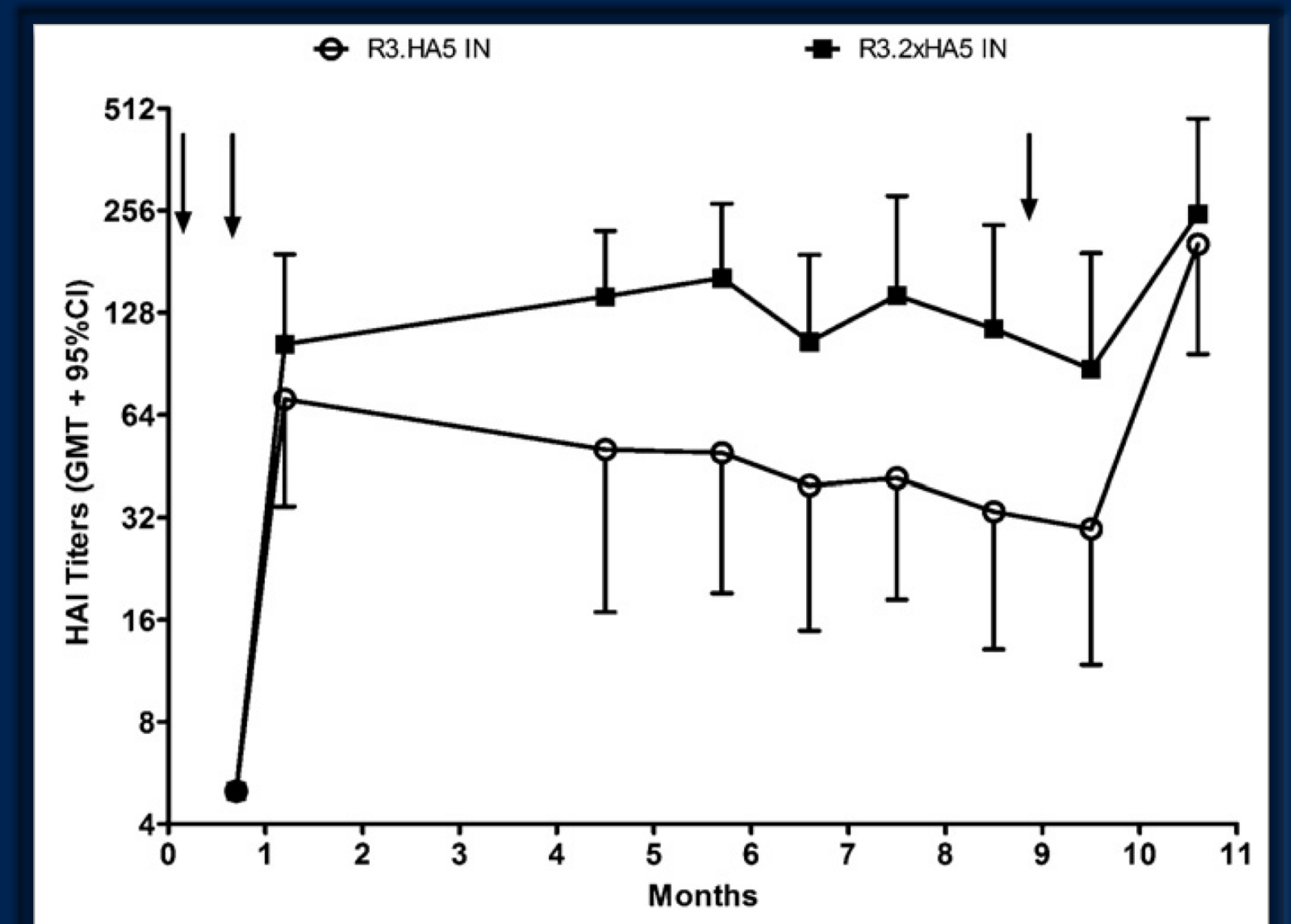
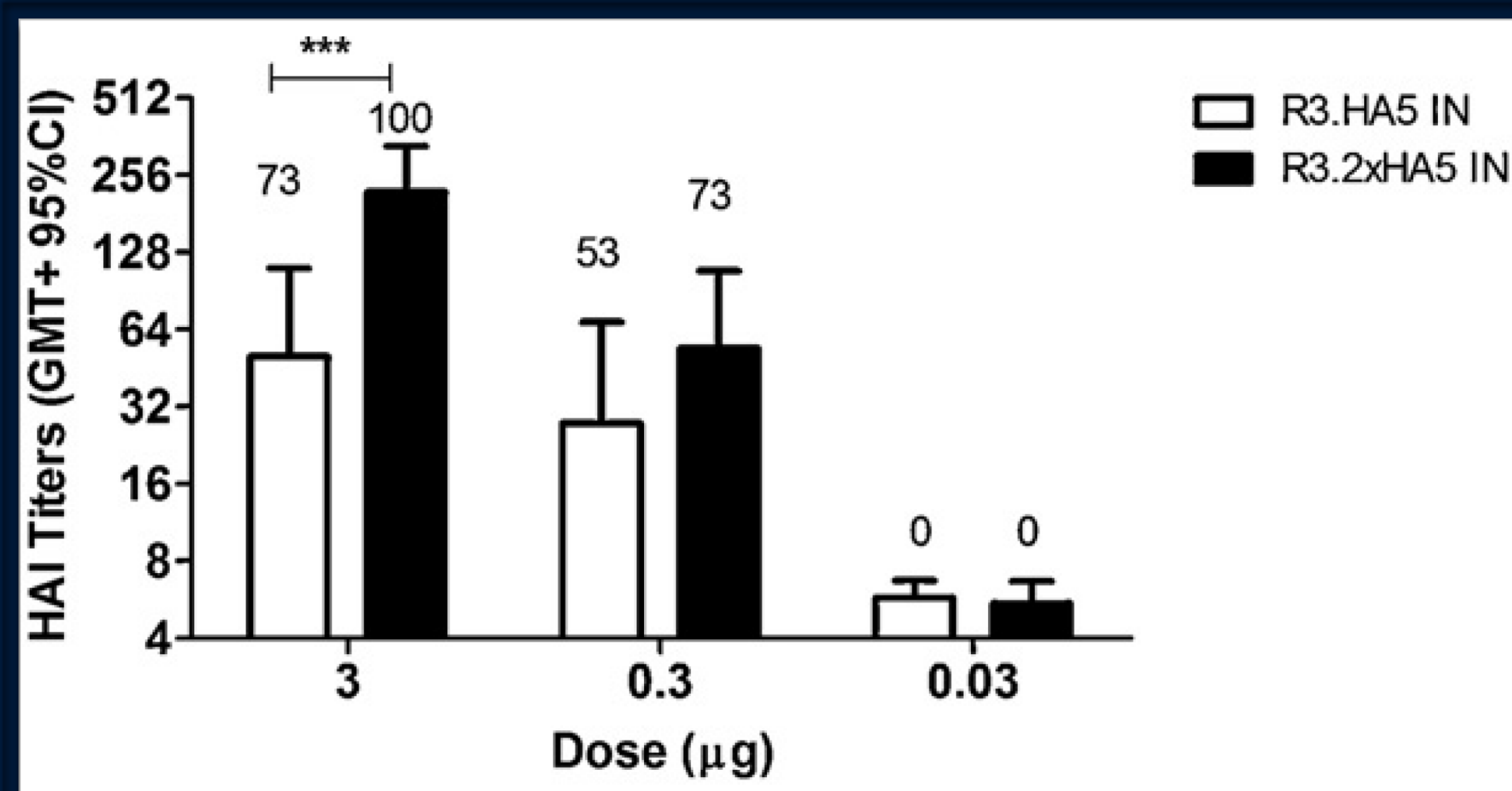
*Quality*



# Contract Management

## *Sample Work Product*

Should we proceed to GMP manufacturing with our current vaccine candidate?





# Contract Management

## *Sample Work Product*

**Should we proceed to GMP manufacturing with our current vaccine candidate?**

- ◉ Review all available data
  - ◉ Mouse immunogenicity and ferret challenge studies
  - ◉ Status of all release and stability assays
  - ◉ Characterization data on lab-scale material
- ◉ Evaluate future plans (i.e., understand the program and ask the hard questions)
  - ◉ Are timelines reasonable?
  - ◉ Do they sufficiently understand their product to scale up manufacturing?
  - ◉ Do they have the right internal resources and external partners?
  - ◉ What does the rest of your team think?
- ◉ Approve path forward
- ◉ Monitor monthly invoices and technical reports to ensure the program stays on track



# Program Management

## *My Experience*

- ◉ After 3 years managing development programs at BARDA, wanted to get first-hand experience in developing products
- ◉ Advice from industry veterans: "This is a good experience, but it's only a window into the product development process."
- ◉ **Novavax, Inc.**
  - ◉ Small biotech developing recombinant vaccines using insect cell/baculovirus platform
  - ◉ Portfolio includes vaccines for influenza, respiratory syncytial virus, Ebola virus, along with a novel saponin-based adjuvant
  - ◉ Positions: Senior Program Manager; Associate Director; Director

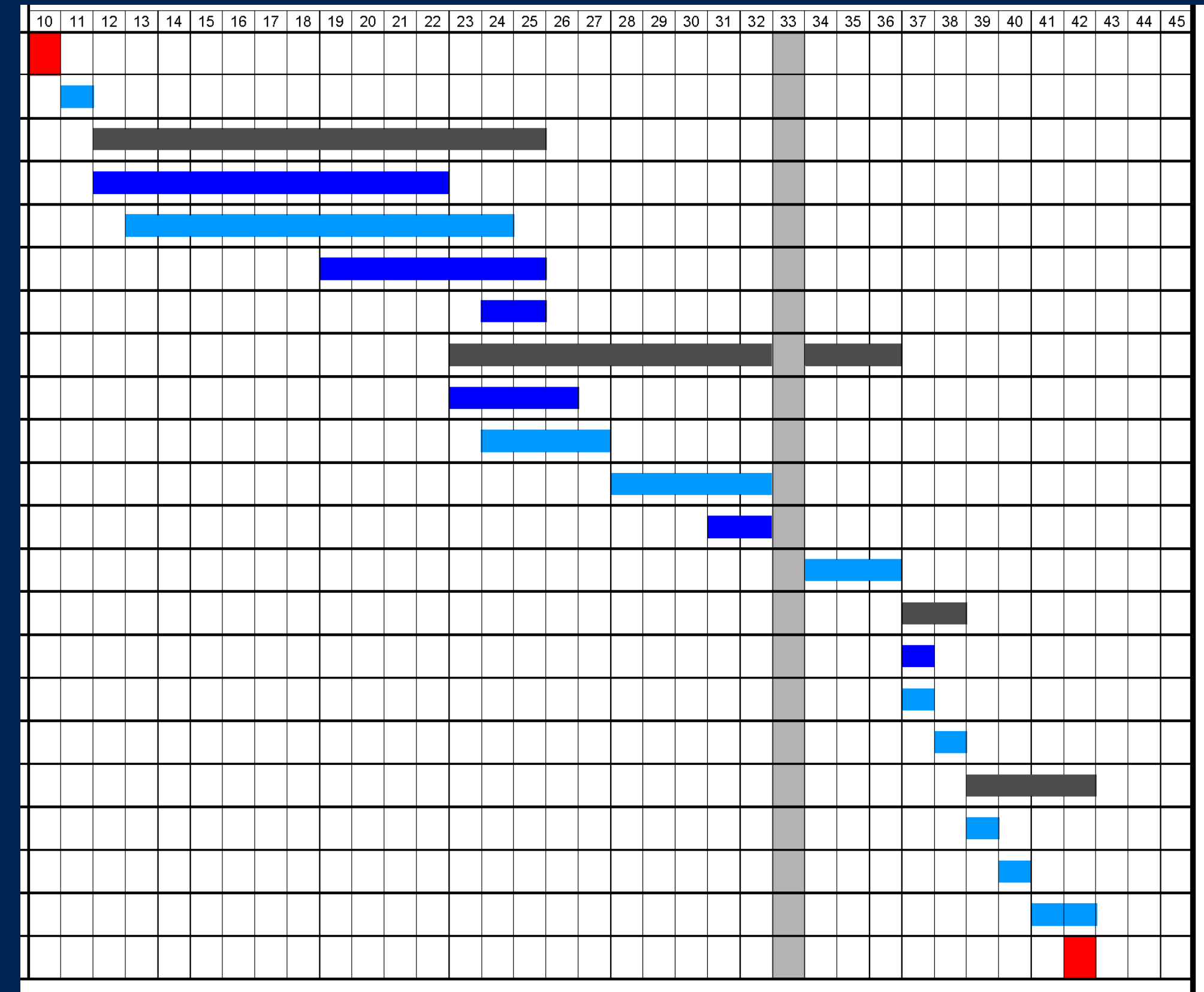




# Program Management

## *A Brief Definition*

- ◉ Develop a plan in partnership with every department
- ◉ Reach consensus on the plan
- ◉ Monitor progress on a frequent basis
- ◉ Review any changes
- ◉ Identify key risks and track resolution
- ◉ Modify plan as necessary without putting corporate objectives at risk
- ◉ Communicate with all levels of the organization





# Program Management

## *Sample Work Product*

- ◉ **October 2013**
  - ◉ Plan for Phase 2 trial in pregnant women to begin fall 2014
- ◉ **Early 2014**
  - ◉ Increasing corporate interest in pediatric Phase 1 trial
- ◉ **Spring 2014**
  - ◉ One year data from Phase 1 trial in older adult subjects shows promise for an annual seasonal RSV vaccine
- ◉ **Fall 2014**
  - ◉ Initiated three RSV clinical trials





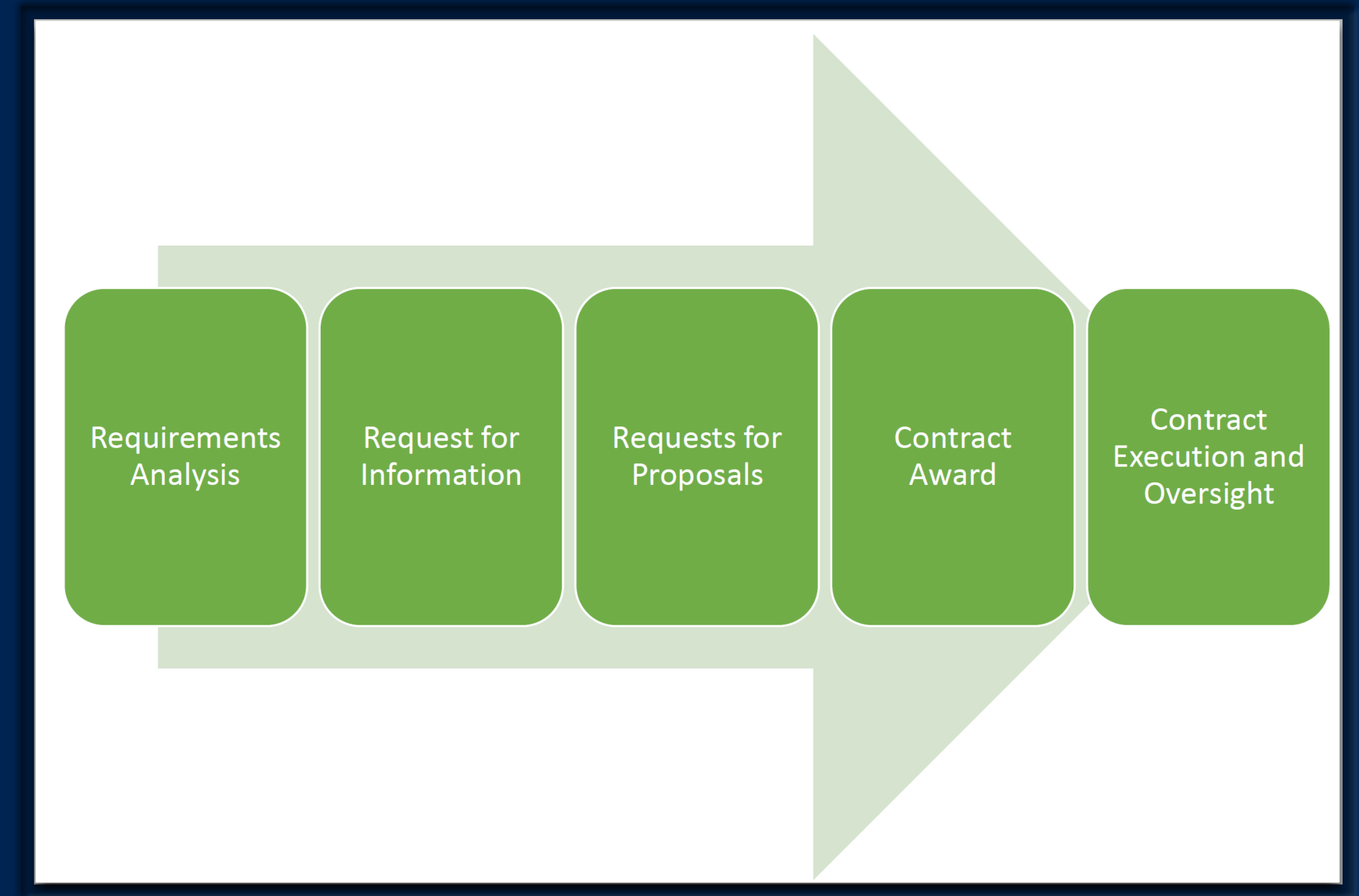
# Contract and Program Management *Opportunities*

- ◉ **Government agencies**

- ◉ NIH
- ◉ BARDA
- ◉ DOD/DTRA, DARPA

- ◉ **Non-profits**

- ◉ Gates Foundation
- ◉ PATH
- ◉ Malaria Vaccine Initiative
- ◉ Henry M. Jackson Foundation





# Closing Thoughts

- ◉ **Begin your next step today**
  - ◉ Science policy: Read up on current issues; follow Congressional hearings
  - ◉ Contract management: Read funding solicitations and agency strategic plans ([grants.gov](https://www.grants.gov))
  - ◉ Program management: Project Management Institute; online trainings
- ◉ **Be flexible**
  - ◉ Unexpected opportunities can be the most rewarding
- ◉ **Be humble**
  - ◉ You will be starting at the bottom
- ◉ **Be confident in your abilities**
- ◉ **Best advice: “You are in charge of your career.”**

