

# The Gain-of-Function Deliberative Process

*Carrie D. Wolinetz, Ph.D.*

*Associate Director for Science Policy*

*Office of the Director*

*National Institutes of Health*

May 5, 2015

# Gain-of-Function (GOF) Studies

**USG supports research aimed at understanding pathogens toward the goal of preventing and treating their infections.**

GOF studies are undertaken to help define the fundamental nature of human-pathogen interactions and thereby have the potential to:

- Enable assessment of the pandemic potential of emerging infectious agents,
- Inform public health and preparedness efforts, and
- Further medical countermeasure development

GOF studies may entail biosafety and biosecurity risks by possibly generating:

- Engineered pathogens that could pose a pandemic threat if they were to be accidentally or intentionally released and
- Information that could be misused to threaten public health or national security

# GOF Deliberative Process and Research Funding Phase

## Deliberative Process

Given the biosafety incidents and renewed concerns regarding laboratory safety and biosecurity, the USG embarked on a deliberative process to **re-evaluate the potential risks and benefits associated with GOF research involving pathogens with pandemic potential.**

## Research Funding Pause

New USG funding will not be released for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

\* *An exception from the research pause may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security.*

# GOF Deliberative Process – Key Components

## Independent Contractor

Gryphon Scientific will  
conduct **Risk and Benefit  
Assessments** of GOF studies

## National Academies

Convene **public forums** to  
generate broad discussion  
and hear public feedback  
from stakeholders

## NSABB

Serves as the **official  
advisory body** for providing  
advice on oversight of this  
area of dual use research

**USG Gain-  
of-Function  
Policy  
Process**

# GOF Deliberative Process – Opportunities for Public Engagement

## NSABB

Held two public meetings (Oct 22 & Nov 25) that included discussion on:

- Potential risks, benefits, and alternatives to GOF studies
- Strengths and limitations of biological risk & benefit assessments
- Ethical and other considerations

## National Academies

Held a two-day public forum (Dec 15 & 16) that addressed:

- Potential risks and benefits of GOF studies
- Key principles for risk and benefit assessments
- Models for risk and benefit assessments
- Risk mitigation
- Public engagement

A second public forum in early 2016 will include discussion on the NSABB's draft recommendations to the USG.

# The Charge to the NSABB

The USG charged the NSABB with two tasks:

## Task 1

Advise on the design, development, and conduct of risk and benefit assessments of GOF studies

### Deliverable 1

Framework for the design and conduct of risk and benefit assessments of GOF studies

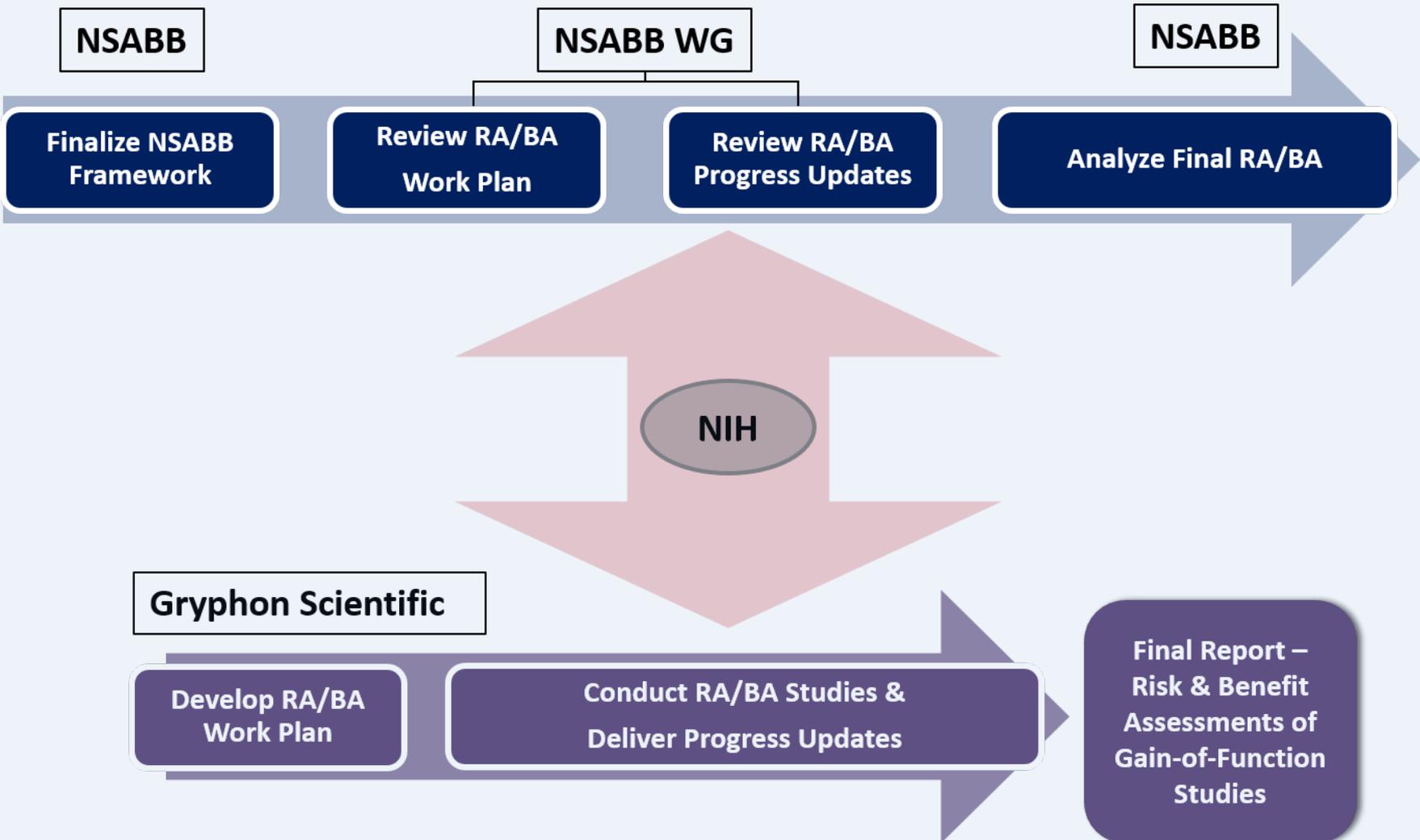
## Task 2

Provide formal recommendations to the USG on the conceptual approach to the evaluation of proposed GOF studies

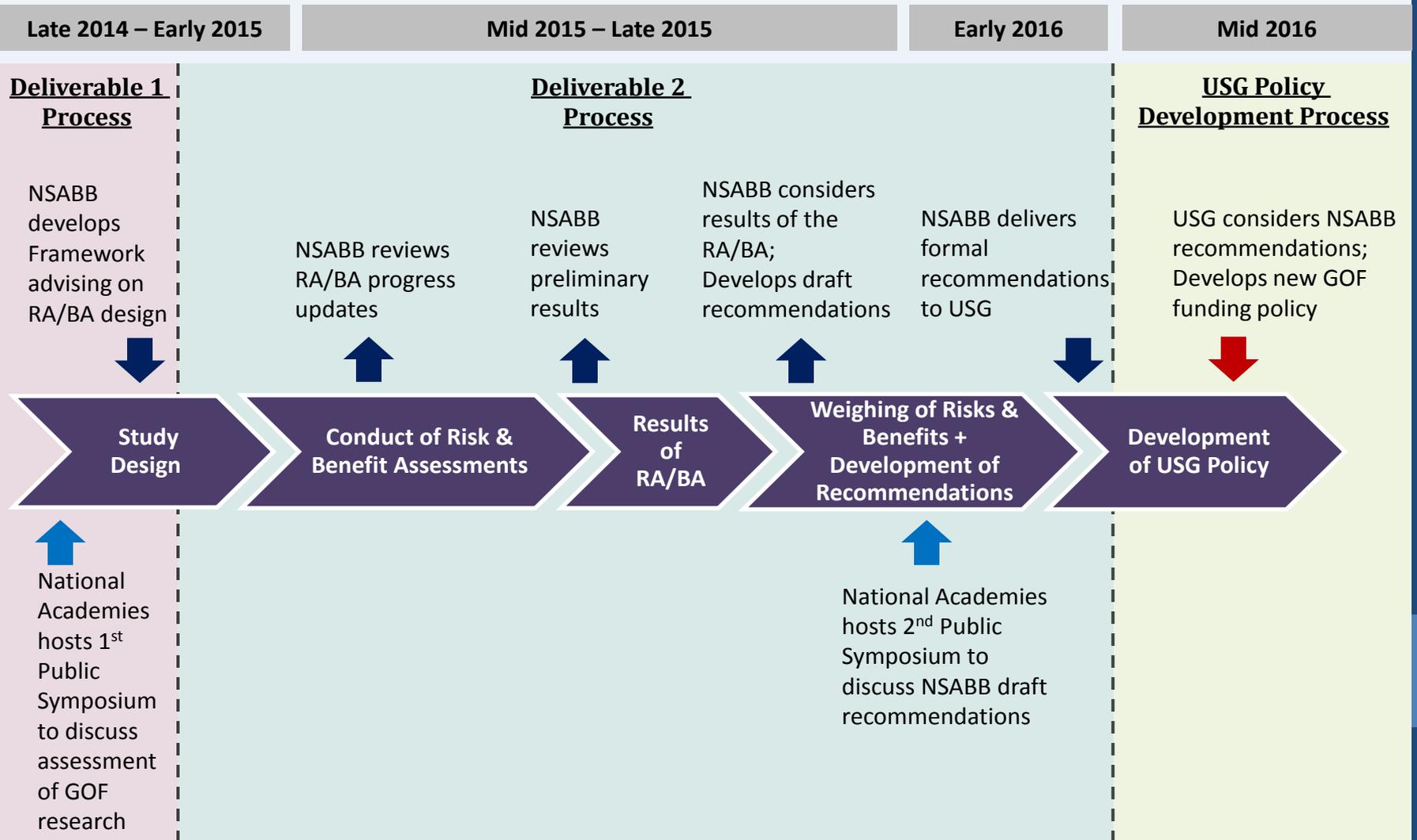
### Deliverable 2

Recommendations to the USG informed by the results of the risk and benefit assessments and information from other relevant sources and disciplines

# Next Steps for the Risk and Benefit Assessments



# GOF Deliberative Process – Estimated Timeline



**Questions?**