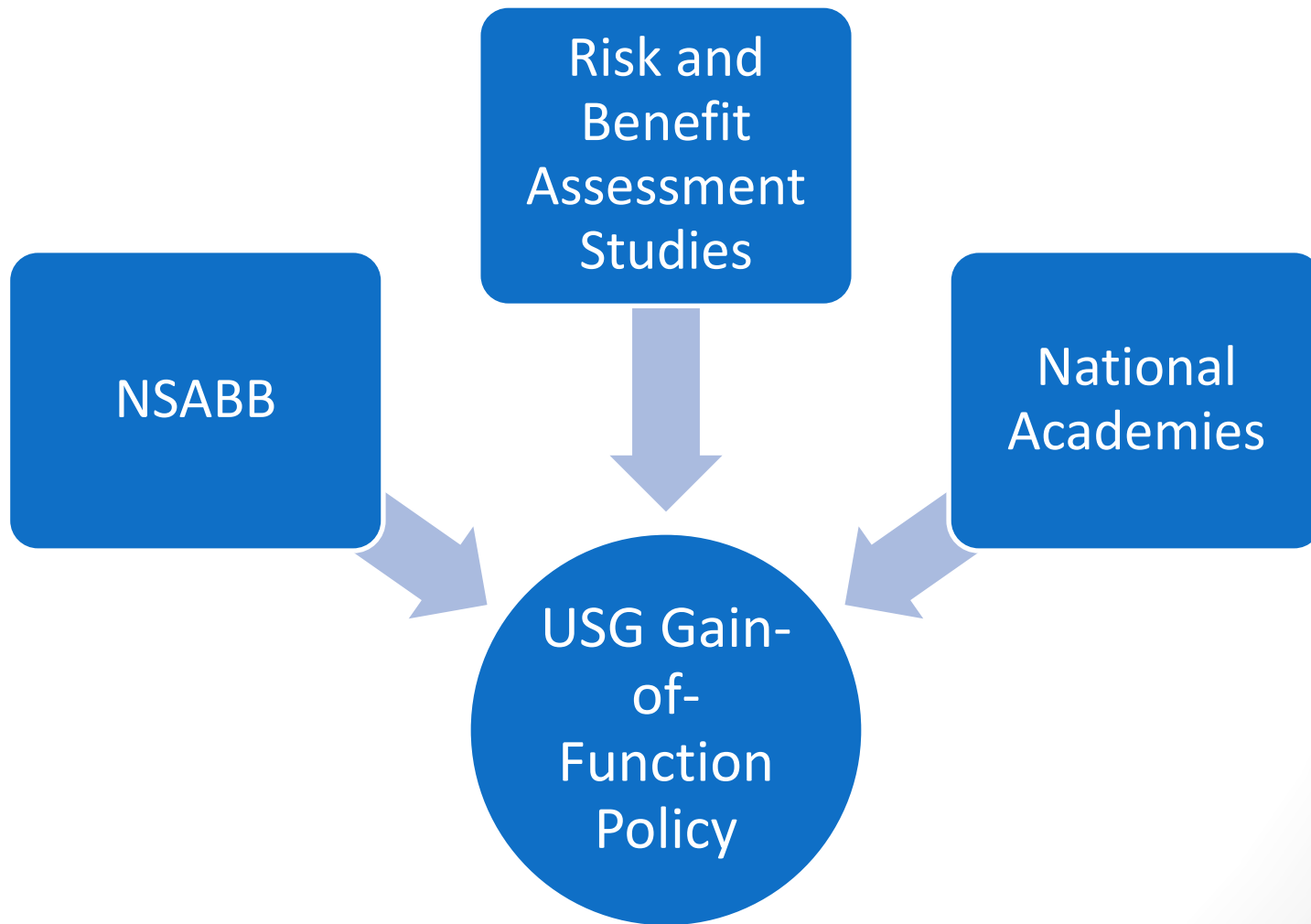


Addressing the Charge to NSABB

Sam Stanley, M.D.

Chair, NSABB

GOF Deliberative Process



Estimated Timeline

Oct-Nov 2014

NSABB deliberates key features of study design

Nov 2014-Jan 2015

NSABB considers National Academies input & advises on draft study design

Early 2015

NSABB periodically assesses progress & reviews preliminary results

June 2015

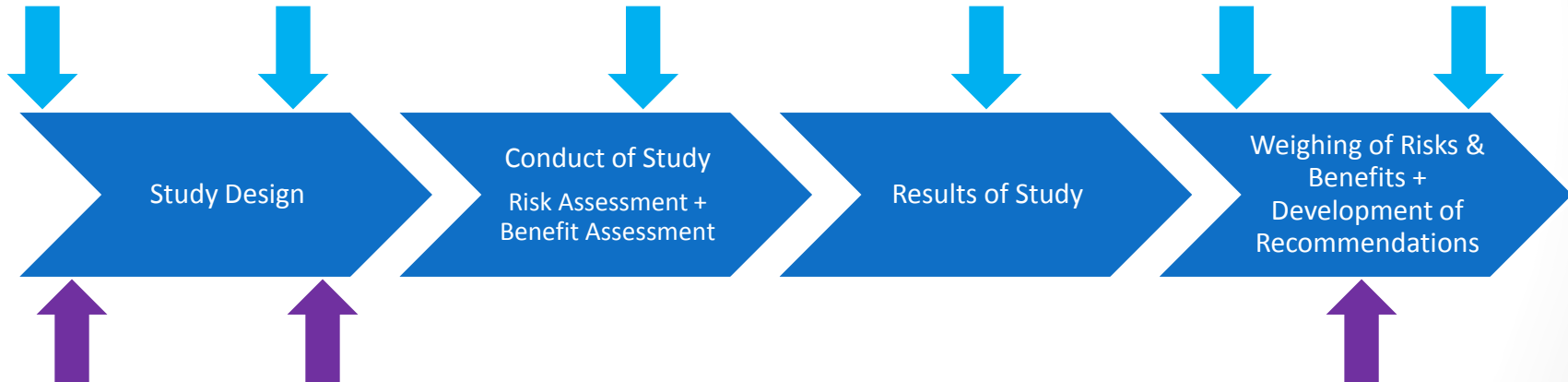
NSABB reviews final results

June 2015

NSABB analyzes & discusses results → Develops draft recommendations

August 2015

NSABB delivers final recommendations to USG



Dec 2014

National Academies host Public Symposium to discuss assessment of GOF research

Jan 2015

National Academies provide Symposium Summary

July 2015

National Academies host Public Symposium to discuss NSABB draft recommendations & provide Symposium Summary

Charge to NSABB

- NSABB is to:
 - Advise on the design, development, and conduct of risk and benefit assessment studies
 - NSABB is to provide recommendations to the USG on a conceptual approach to the evaluation of proposed GOF studies
- In developing its recommendations to the USG, the NSABB will consider:
 - The results of the risk and benefits assessments
 - Spectrum of potential risks and benefits associated with such studies
 - Any alternative methods that may be employed to yield similar scientific insights or benefits, while reducing potential risks.
 - Discussions hosted by the National Academies, and
 - Any additional consultations with relevant subject matter experts, as needed, to ensure that appropriate expertise is brought to bear on the issues.

Advising on the Risk and Benefit Assessments

In advising on the design and conduct of the risk and benefits assessments, NSABB will:

- Advise on the assumptions to be included in the risk assessment, including those related to:
 - Characteristics of the pathogens with pandemic potential in question
 - Proposed experiments to be assessed
 - Biosafety practices and containment features to be utilized for the studies, and
 - Inventories of the pathogens
- Evaluate the methodologies, scope, and scenarios to be used in the risk assessment
- Consider the adequacy of the scenarios in the risk assessment and propose additional scenarios to address other concerns or factors, as appropriate
- Consider the discussions and input generated during a National Academies forum

Advising on the Risk and Benefit Assessments

In advising on the design and conduct of the risk and benefits assessments, NSABB will:

- Advise on the assessment of the benefits, including the types of benefits that should be examined and methods for examining them
- Provide advice at key milestones in the conduct of the risk and benefit assessment studies

NSABB Deliverables

1. Advice on the design, development, and conduct of risk and benefit assessments.
2. Formal recommendations on the conceptual approach to the evaluation of proposed GOF studies.