

## WHO WE ARE 1

Developers of biotherapeutics face numerous challenges that can be encountered while executing manufacturing runs, IND-enabling studies, IND submissions, and initiation of a clinical trial. Academic laboratories and small business enterprises may not yet have the full scope of expertise and resources needed to translate and guide their therapeutics into the clinic.

NIH Blueprint Neurotherapeutics Network (BPN) serves as a pipeline between the typical endpoint of NIH funded research and the beginning of industry drug development. Following the success of the BPN-Small Molecules program, NIH launched **The Blueprint Neurotherapeutics Network for Biologics (BPN-Biologics) program** to address these obstacles in development of a variety of **biologics**:

- **Biotechnology products and biologics-based therapies (e.g., antibodies, peptides, proteins)**
- **Gene-based therapies (e.g., oligonucleotide and viral-vectors)**
- **Cell therapies**
- **Other novel emerging therapies (e.g., microbial and microbiome therapies)**

## PROGRAM GOALS 2

*"Combine Strengths of NIH and Industry Expertise for Neuroscience Drug Discovery"*

Expedite emergence of new biotherapeutics to the market

Provide non-dilutive funding and resources (contracts, consultants) that are often lacking in research community.

De-risk potential therapeutics to the point that industry will invest in them, allowing potential new therapeutics to reach patients efficiently

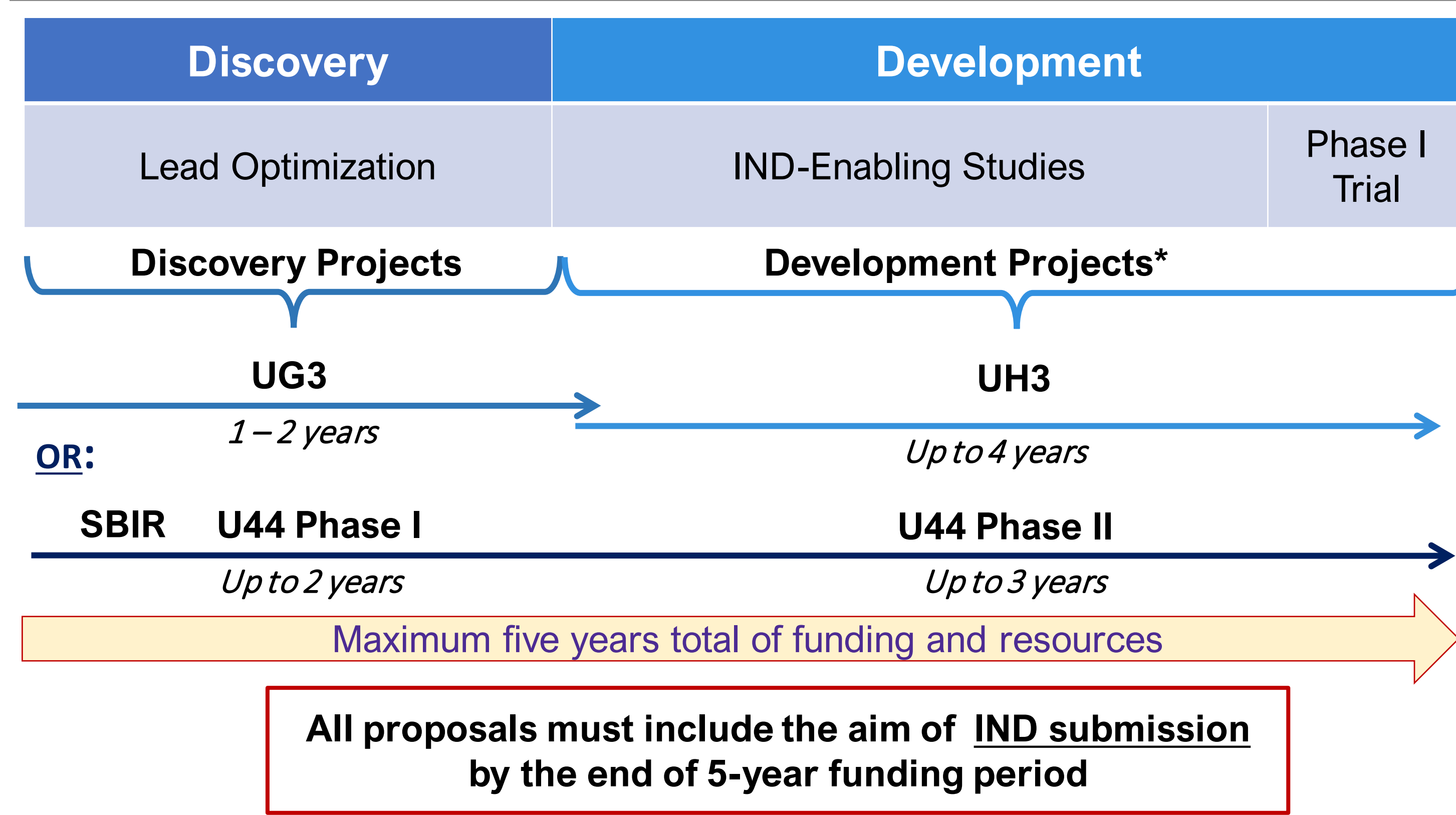
Preserve PI/Institution's Intellectual Property

## FUNDING OPPORTUNITIES 3

FOA/Mechanism	Mechanism Name	Length	Budget
<b>PAR-21-163: UG3/UH3</b>	Research Project, Cooperative Agreements	Up to 5 years total (UG3- up to 2 years, UH3 – up to 4 years)	Not limited, must reflect the actual needs of the proposed project
<b>PAR-21-233: U44</b>	Small Business Innovation (SBIR) Cooperative Agreements *Fast-track	Phase I: Up to 2 years Phase II: Up to 3 years	Phase I: Up to \$500,00 per year Phase II: Up to \$1,500,000 per year. Must be reasonable and appropriate

The next application due dates for PAR-21-163 and PAR-21-233:  
August 9, 2022, February 9, 2023, August 9, 2023, February 9, 2024.

## ENTRY STAGES AND MECHANISMS 4



## ENTRY CRITERIA 5

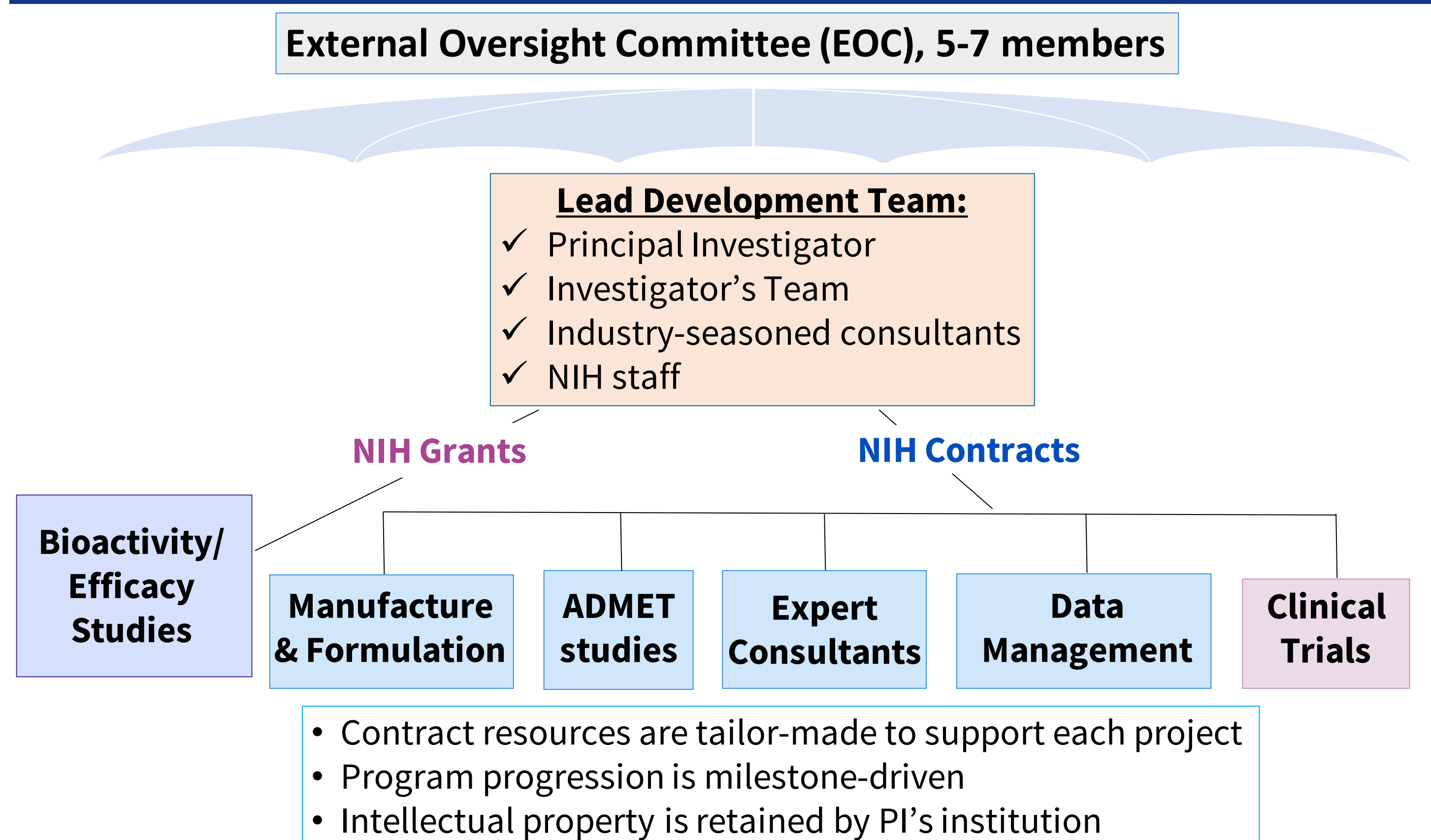
Discovery Stage	Development Stage
<ul style="list-style-type: none"> <li>• Identified several lead biologics ready to be optimized/down-selected</li> <li>• Sufficient preliminary <i>in vivo</i> efficacy and target engagement data using agent(s) in relevant animal model(s)</li> <li>• Key <i>in vitro</i> and <i>in vivo</i> assays suitable to drive characterization/optimization has been generated</li> <li>• No obvious legal/IP constraints.</li> </ul> <p><b>End Goal:</b> A clinical candidate with appropriate bioactivity, bioavailability, stability, ready to manufacture.</p>	<ul style="list-style-type: none"> <li>• Sufficient data linking the putative therapeutic target to the proposed disease indication</li> <li>• Lead biologic ready for manufacturing and IND-enabling studies</li> <li>• Rational research activity plan essential for pre-IND submission</li> <li>• Demonstration of the PD/PI's institution ability to develop the proposed biologic towards the clinic</li> </ul> <p><b>End Goal:</b> Submission of IND package (and optional Phase I Clinical Trial initiation).</p>

## MILESTONE PROGRESSION 6

- Clear quantitative, definitive milestones are essential
- Go/No-Go points will be discussed and established prior to the Notice of Award
- External Oversight Committee (EOC) will assess milestone progress and recommend which projects will advance from UG3 → UH3 (SBIR U44 Phase I → Phase II).
- Applications must describe all activities to bring the project up to the clinical trial stage (regardless of entry point) within a maximum of 5 years of BPN-Biologics' funding and support.



## INFRASTRUCTURE AND EXPERTISE 7



## CONTACT INFORMATION 8

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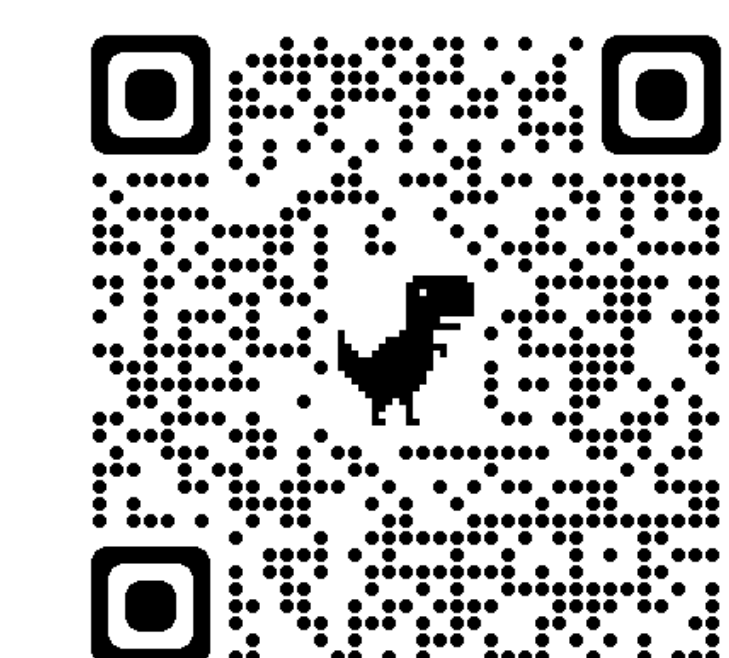
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<https://neuroscienceblueprint.nih.gov/neurotherapeutics/bpn-biologics>

Visit our website:



For project-specific questions, please email your inquiries to: [Bpn-biologics.questions@nih.gov](mailto:Bpn-biologics.questions@nih.gov)

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