# Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development for Disorders of the Nervous System

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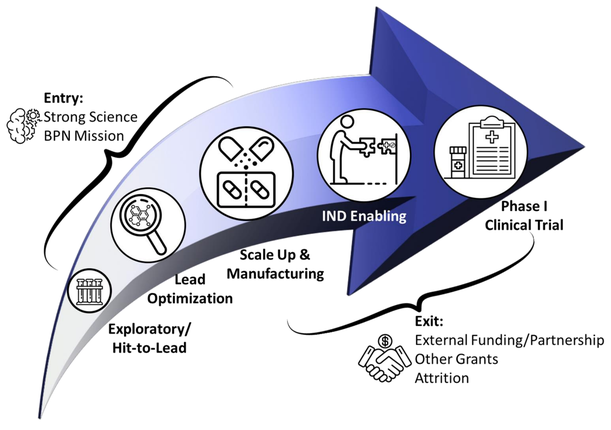
## PROGRAM OVERVIEW

To boost drug discovery and development efforts in the neuroscience field, the division of translational research (DTR) within NINDS, and in collaboration with other NIH-institutes, launched a series of translational programs to promote neuroscience drug discovery and development efforts to mitigate the current pipeline gaps. In this poster, we outline NINDS/DTR-BPN funding mechanism and resources available to academia and industry neuroscientists to accelerate their translation research into new therapies and support their ongoing preclinical development in the neuroscience field. The BPN (Blueprint Neurotherapeutic) program provides non-dilutive funding for small molecule or biologics (not covered in this poster) drug discovery and development, from exploratory, hit-to-lead through phase I clinical testing. This is accomplished through a combination of grant funding and access to a full range of BPN-sponsored contractors (medicinal chemistry, pharmacokinetics/ADME, toxicology, drug manufacturing, drug formulation and phase I clinical trials) and to BPN funded consultants with extensive pharma experience. The poster describes the key features and expertise of the BPN program to de-risk projects and solve challenges and examples that reached the development finish line (clinical trials, partnership, or out-licensing).

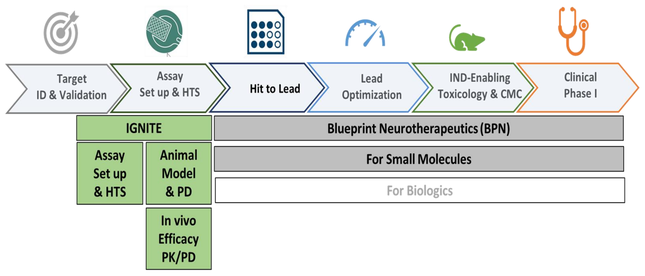
## PROGRAM VISION

To de-risk potential therapeutics to the point that industry will invest in them allowing potential new drugs to reach patients efficiently.

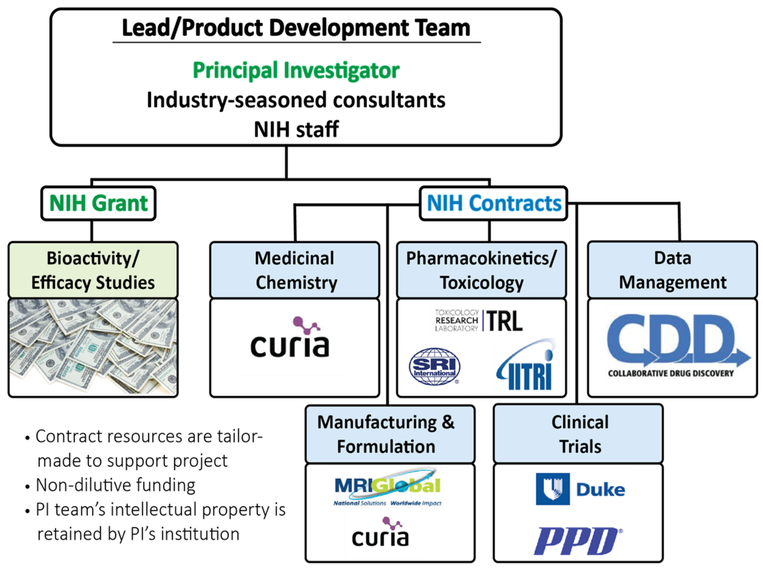
To provide grant funding and necessary resources (contracts, consultants, etc.) that are typically lacking in the research community




Combine Strengths of NIH and Industry Expertise for Small Molecule Neuroscience Drug Discovery & Development"




## BPN PROJECT ORGANIZATION

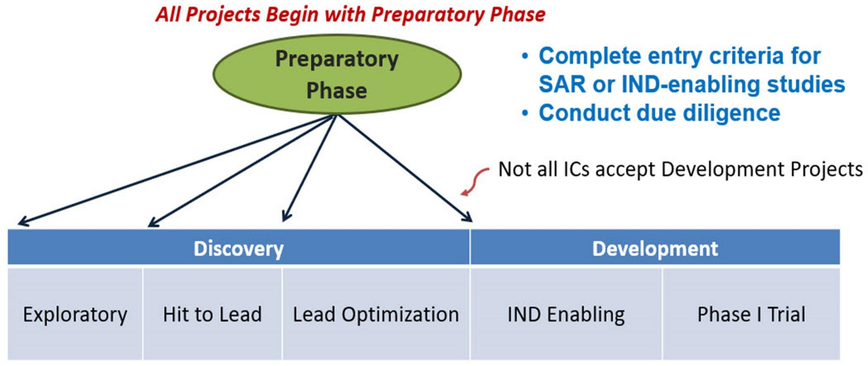



- Contract resources are tailor-made to support project
- Non-dilutive funding
- PI team's intellectual property is retained by PI's institution

***Program progression is milestone driven***

## PROJECT CAN ENTER ANY PRECLINICAL STAGE

***All Projects Begin with Preparatory Phase***




| General (UG3/UH3) PAR-20-122 | SBIR (U44-I/II) PAR-20-111 |
|---|---|
| UG3: Up to $300K direct costs x 1 yr<br>UH3: Up to $1.5M/yr direct costs x 4 yrs | Phase I: Up to $500K/yr*($700K total across ≤2 yrs)<br>Phase II: Up to $1.5M/yr ($3M total across ≤3 yrs) |

## ENTRY CRITERIA

### Discovery

**Disease Biology**
- Novel target for the disease
- Strong biological validation
- Feasible path to the clinic

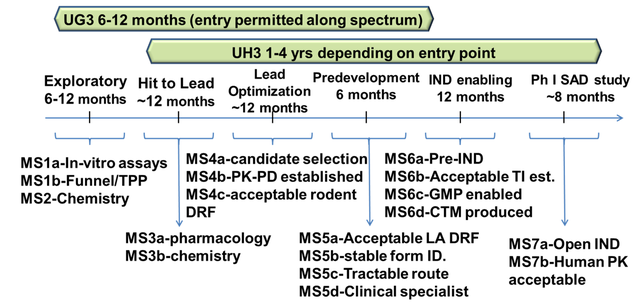
**Assays**
- Robust in-vitro assay for optimization
- Strong confirmatory assays

**Compounds**
- Project must require medicinal chemistry
- Amenable to chemistry
- IP free of obvious roadblocks

### Development

**Fully Optimized Compound**
- Strong data linking target to disease
- Biological & ADMET activity appropriate for intended clinical use
  - Efficacy/PD when delivered by clinically intended route
  - Fully profiled, defensible ADMET results
- Feasible path to the clinic
- IP free of obvious roadblocks

## MILESTONE PROGRESSION BY STAGE



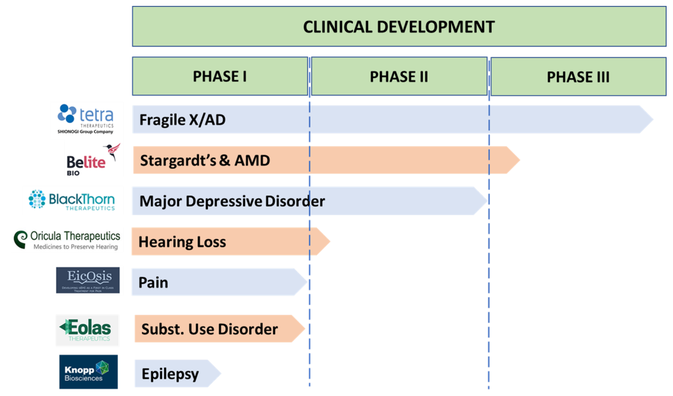

***Grant duration maximum of 5 years for the combination of the UG3 and UH3 phases***

## INTELLECTUAL PROPERTY

The Blueprint program goal is to create a licensable product. Prior to grant award, PI's institution must have up-front IP agreements in place with all potential inventors.

These agreements must address; 1) Who will hold title to IP on new chemical matter/use; 2) Royalty arrangements
IP agreements should aim for unencumbered IP.

## BPN PROJECTS SUCCESSFUL PROGRESSION




**10 projects have announced partnership or additional industry funding since joining the BPN**

## PARTICIPATING NIH INSTITTUTES

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