NIH Blueprint Neurotherapeutics Network (BPN)

https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-neurotherapeutics-bpn-network

WHO WE ARE 1

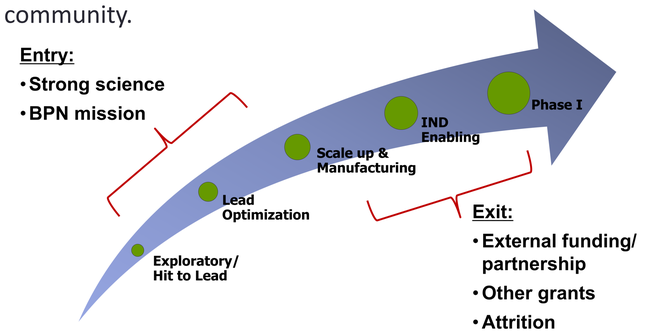
"Grand Challenge to Provide Grant Funding and Resources to Facilitate Small Molecule Drug Discovery and Development to Treat CNS Disorders"

In 2011, the NIH Blueprint for Neuroscience Research, a consortium of 15 NIH Institutes and Centers that support neuroscience research, launched the Blueprint Neurotherapeutics Network (BPN).

The BPN serves as a pipeline between the typical endpoint of NIH-funded research and the beginning of industry drug development. The BPN provides neuroscience researchers with funding and access to a full range of industry-style drug development services and expertise. The program is intended for projects requiring medicinal chemistry optimization and CRO support through phase I clinical testing. Each project is directed by a Lead Development Team composed of the principal investigator, industry consultants hired by NIH, and NIH staff.

PROGRAM GOALS 2

- 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 our research community.



WHAT WE OFFER 3

- BPN provides non-dilutive funding to investigators from academia and industry.
- Investigators retain rights to intellectual property.
- Access to CRO's under contract to NIH.
- Access to consultants and staff with extensive industry experience covering the major needs:
  - Assay development expertise, pharmacology, medicinal chemistry, pharmacokinetics, toxicology, process research, chemical/formulation development, and Phase I clinical testing.
- Fast track SBIR U44 grants for small businesses.

ENTRY STAGES AND MECHANISMS 4

All Projects Begin with Preparatory Phase

Preparatory Phase

- Complete entry criteria for SAR or IND-enabling studies
- Conduct due diligence

Not all ICs accept Development Projects

Discovery			Development	
Exploratory	Hit to Lead	Lead Optimization	IND Enabling	Phase I Trial

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

Next Anticipated Application Due Date : August 11, 2020

Participating ICs: NINDS, NIA, NIAAA, NIDA, NIMH, NICHD, NIDCR, NCCIH, NEI

ENTRY CRITERIA 5

Discovery

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

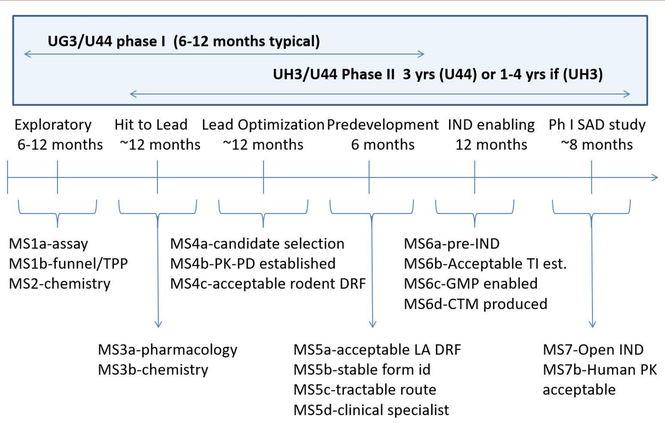
Assays
- Robust in-vitro assay for optimization
- Strong confirmatory assays

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

Development

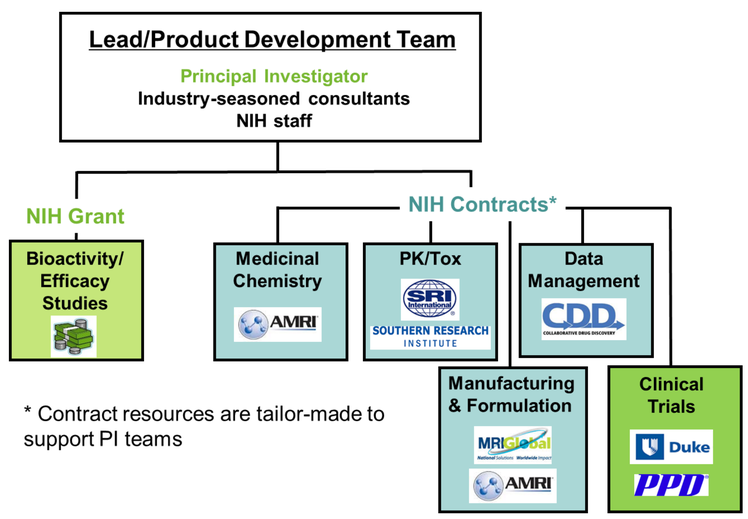
Fully Optimized Compound
- Strong data linking target to disease
- Biological & ADMET activity appropriate for intended clinical use
  - Efficacy/PD when delivered by clinically intended route
  - Fully profiled, defensible ADMET results
- Feasible path to the clinic
- IP free of obvious roadblocks

MILESTONE PROGRESSION BY STAGE 6



Grant duration maximum of 5 years for the combination of the both phases

INFRASTRUCTURE, EXPERTISE, & FUNDING 7



* Contract resources are tailor-made to support PI teams

BPN PROJECTS IN THE NEWS 8

AGENEBIO™

AgeneBio Announces Additional Funding to Advance Novel GABA-A Therapeutic Program to Address Alzheimer's and Other CNS Conditions

- AgeneBio has been awarded nearly $500,000 from the Alzheimer's Drug Discovery Foundation and has been selected to receive a Small Business Innovation Research grant from the National Institute on Aging of up to $2.9 million

EicOsis

EicOsis Announces FDA Acceptance of IND Application for EC5026, the First Soluble Epoxide Hydrolase Inhibitor to Treat Pain

tetra

Tetra Discovery Partners Initiates Phase 2 Clinical Trial of BPN14770 in Patients of Early Alzheimer's Disease

Belite BIO

Belite Bio Announces FDA Approval of Investigational New Drug (IND) for Phase 1 Clinical Trial of LBS-008 to Treat Macular Degeneration and Stargardt Disease

CONTACT INFORMATION 9

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