



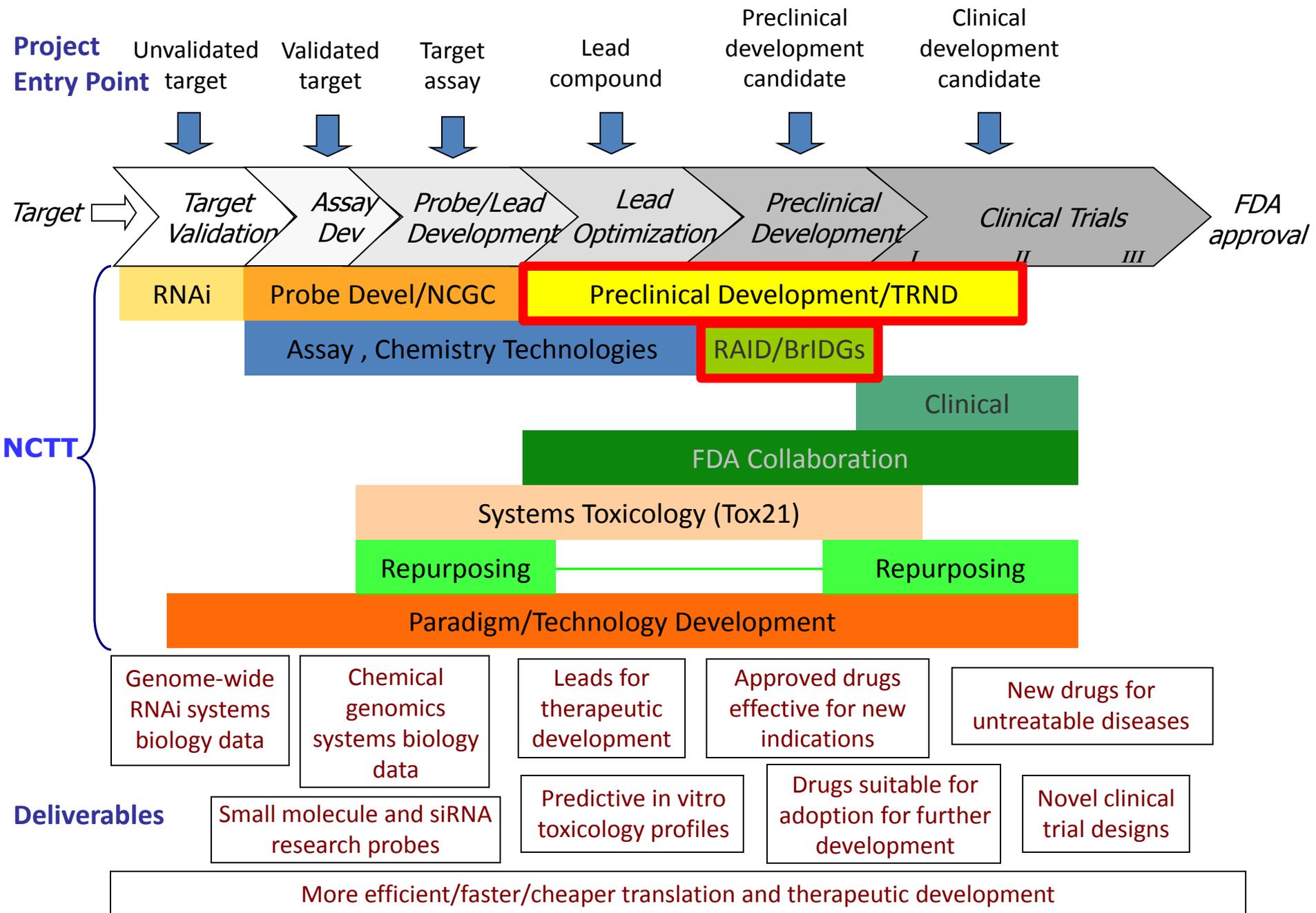
# Translational Therapeutics Development: TRND and BrIDGs



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Gene Transfer and Rare Disease Workshop  
9/13/12



# NCATS Division of Preclinical Innovation: An Integrated Pipeline



# Bridging Interventional Development Gaps (BrIDGs)

- Model: Collaboration between NIH staff with drug development expertise and extramural labs with clinical candidate identified. Former NIH-RAID Program
- Projects:
  - Enter at clinical candidate stage of development
  - Modalities: small molecules, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins
  - Gap analysis performed followed by data generation using government contracts to generate data necessary for IND filing
  - IND filing and clinical trial funding PI's responsibility
- Eligible Applicants:
  - Academic (US and Ex-US), Non-Profit, Government Lab, SBIR eligible businesses
- Intellectual Property:
  - Most projects that enter have an existing patent estate belonging to Collaborator

<http://ncats.nih.gov/bridgs.html>

# Bridging Interventional Development Gaps (BrIDGs)

NIH-wide mandated program intended to reduce some of the common barriers between laboratory discoveries and clinical trials of new therapeutic entities.

- Supported by the NIH Common Fund.
- Provides access to contract services for:
  - Production/bulk supply.
  - GMP manufacturing.
  - Formulation.
  - Pharmacokinetic testing.
  - Animal toxicology.
  - Manufacture of clinical trial supplies.
  - Product development planning and advice in IND



preparation.



<http://nctt.nih.gov/bridgs/>

# BrIDGs Summary

- 180 applications submitted since 2005
  - 30 approved
- Status of approved projects
  - 16 completed projects
    - 12 INDs
  - Seven projects are in the clinic
  - Five agents were licensed during or after BrIDGs involvement.

# Gene Therapy Resources

- Vector types (resources supported by GTRP)
  - Adeno-associated virus
  - Lentivirus
- Data Requirements
  - Lead vector with demonstrated optimization
  - In vivo efficacy studies
- Organizations
  - Academic and non-profit labs
  - SBIR-eligible business

## Active and Completed BRiDGs Gene Therapy Projects

Applicant	Organization Name	Agent	Dis Type	Funding	Status
Bankiewicz, Krystof	University of California San Francisco	AAV Vector	Aromatic L-amino acid decarboxylase	NIH CF and NINDS	Active
Bankiewicz, Krystof	University of California San Francisco	AAV Vector	Parkinson's disease	NIH CF and NINDS	Completed
Evans, Christopher	Beth Israel deaconess Medical Center	AAV Vector	Osteoarthritis	NIH Common Fund (CF)	Active

# Therapeutics for Rare and Neglected Diseases (TRND) Program

- Model: Collaboration between NIH intramural labs with preclinical drug development expertise and extramural labs with disease-area / target expertise
- Projects:
  - May enter at various stages of development
  - Taken to stage needed to attract external organization to adopt for final clinical development
  - Serve to develop new generally applicable platform technologies and paradigms
- Eligible Applicants:
  - Academic, Non-Profit, Government Lab, Small Business, or Large Biotech / Pharma
  - Ex-U.S. applicants accepted
- Intellectual Property:
  - Partnerships are creative
  - TRND may generate intellectual property

<http://trnd.nih.gov>

# Which Program is a Fit?

BrIDGs	TRND
Contract Resource	Team-based Collaboration
PI must have a lead agent	PI may start with lead optimization
No clinical trial support provided	Some clinical trial support provided
IP retained by owner	NIH may generate IP
Universal disease scope	Rare and neglected tropical diseases only
Investigator prepares IND	Regulatory affairs assistance provided

# Questions? Various Points of Contact...

**TRND:**  
**BrIDGs:**

Applications (9/30/2012): <http://trnd.nih.gov/>

Applications (2/2013): <http://nctt.nih.gov/bridgs>



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