NCATS Advisory Council
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Concept Clearance

R&D CONTRACT SUPPORT FOR NCATS TRANSLATIONAL SCIENCES

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Goal

To obtain access to R&D services in various pre-clinical and clinical therapeutic development areas. These services would complement internal scientific and acquisition resources within NCATS.

Services may include:

- *Lead optimization*
- *Animal disease model development*
- *Assay and process design and validation*
- *Chemistry, Manufacturing, and Controls (CMC) development*
- *Biologics manufacturing*
- *Investigational New Drug (IND)-enabling safety study completion*
- *Regulatory strategy and filing*
- *Clinical trials conduct (in accordance with the NCATS mission and congressional authorization)*

Outcome

With its own contracts the Center can independently advance promising science when private sector funding is inadequate.

The contracts will aid in de-risking promising targets and therapeutics. NCATS has leveraged contract resources previously to:

- Identify and develop new candidate therapeutics
- Generate data for IND filings
- Conduct clinical studies

Success will be measured by the advances enabled by the contracts, e.g. publication of new approaches, achievement of regulatory milestones, and out-licensing of technologies.

Initiative Highlights

- DPI would issue RFPs for medicinal chemistry, animal model development, CMC, PK/Tox, regulatory and clinical services

- The awarded contracts would empower current and future NCATS programs to meet their missions
  - DPI programs such as TRND, BrIDGs, Chemistry Technology and Matrix Screening currently leverage external sources for R&D study execution.

Highlights Continued

- The awarded contracts would increase the flexibility and efficiency of these programs
  - Standing contracts may permit more rapid initiation of studies
  - NCATS-managed contracts would avoid reliance on scope-limited contracts managed by other ICs.

- The awarded contracts would solidify the non-dilutive nature of NCATS collaborations and resource awards
  - NCATS contracts will include Determination of Exceptional Circumstance clauses. DECs protect third party IP from the threat of dilution.

Highlights Continued

- The awarded contracts would complement internal capabilities and other acquisition mechanisms
  - CROs would be used when in-house resources are insufficient (e.g. GMP/GLP studies) and when time, cost, expertise, and capability considerations identify CROs as the best option.