
Welcome – the webinar will begin at the top of the hour!
TRxA BRIDGE Awards
Webinar 27JAN2026

CRITICAL PATH INSTITUTE

PKD FOUNDATION
Polycystic Kidney Disease

TRxA BRIDGe Awards - In collaboration with the PKD Foundation

C-Path's Translational Therapeutics Accelerator Bridging Research and Innovation in Drug Development Grants

Including a new, dedicated Polycystic Kidney Disease (PKD) funding track

c-path.org

TRxA is a **global** drug discovery and development program that supports **academic scientists** in advancing new, cutting-edge **therapeutics** from the lab to the clinic.

New in 2026: PKD Foundation Track

- Partnership with the Polycystic Kidney Disease (PKD) Foundation
- Designed to accelerate high-quality translational therapeutics for PKD
- Combines:
  - **TRxA's nonprofit accelerator model and regulatory expertise**
  - **PKD Foundation's disease expertise, patient focus, and scientific leadership**
- Represents a significant new investment in PKD drug development
- The 'traditional' C-Path track is also available, accepting applications in the areas of rare and orphan disease, pediatrics and brain health

Why TRxA and PKDF are Partnering

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PKD remains an area of high unmet medical need with limited disease-modifying therapies

Many promising academic discoveries fail to progress due to:

- Translational gaps
- Lack of coordinated funding and expertise

PKD FOUNDATION
Polycystic Kidney Disease

This partnership aims to:

- De-risk PKD programs earlier
- Strengthen development plans with translational and regulatory input
- Accelerate projects toward investor- and partner-ready data packages
- Leverage expertise of the PKD Foundation and C-Path's Polycystic Kidney Disease Outcomes Consortium

TRxA Team

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Maaike Everts
Executive Director

Mark Drew
Director of Drug Discovery and Development

Michelle Morgan
Associate Director

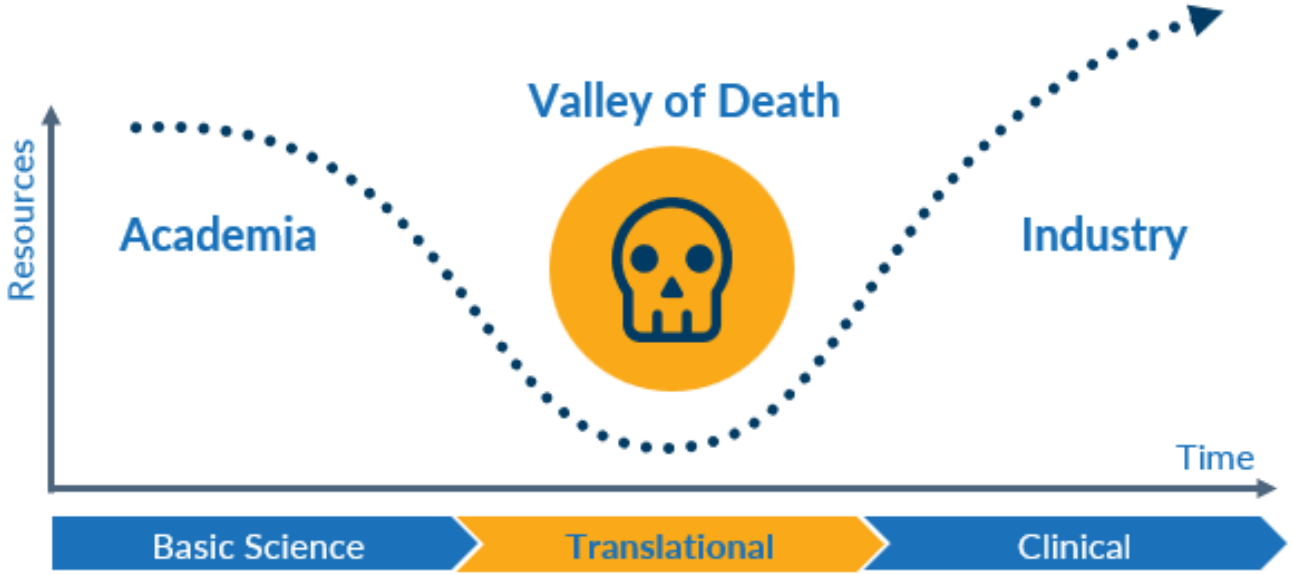
Kyla Oetting
Project Coordinator II

Samantha Wilkins
Project Manager

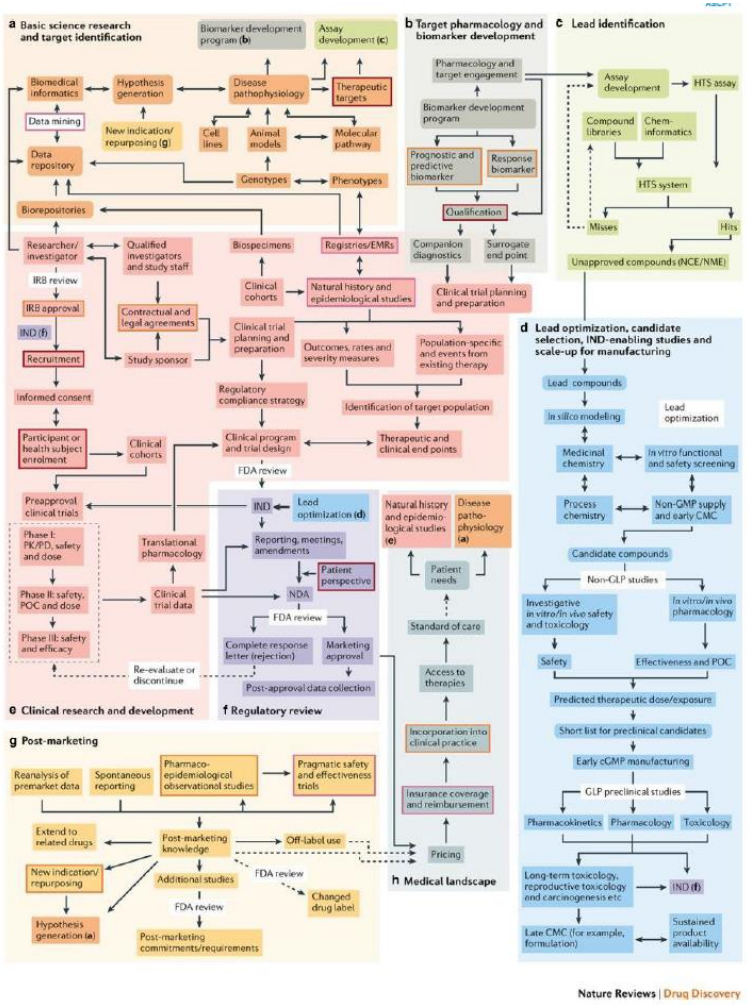
The Drug Development Gap

The Reality: Promising academic research with the potential to transform lives too often stalls before reaching the clinic

Without coordinated **funding, infrastructure, and regulatory expertise** to move forward, these discoveries often fall into the *"drug development valley of death,"* never advancing into real treatments for patients



Complexity of Translational Science



Interplay of disciplines and ecosystems:

- Basic science research and target identification
- Target pharmacology and biomarker development
- Lead identification
- Lead optimization, candidate selection, IND-enabling studies and scale-up for manufacturing
- Clinical research and development
- Regulatory review
- Post-marketing
- Medical Landscape

C.P. Austin, Opportunities and challenges in translational science; *Clin Transl Sci.*, 2021;14:1629
doi: 10.1111/cts.13055

Bridging the Gap: Accelerators Can Reduce Risk

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Bring experts together early – scientists, clinicians, and industry partners collaborate from the start

Focus on the right targets – making sure the science is aimed where it can truly impact patients

Strengthen the research plan – adding outside input to refine experiments and avoid dead ends

Provide rigorous testing – ensuring new ideas are thoroughly evaluated before moving forward

Engage industry early – so promising projects are aligned with what pharma and biotech can advance

Build with regulators in mind – laying the groundwork for future approvals from day one

Not all Accelerators are Created Equal

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C-Path's Translational Therapeutics Accelerator (TRxA) has **global** reach, **supporting academic scientists** to advance new **therapeutics** from the lab to the clinic.

Unlike commercial drug accelerator programs, TRxA is **nonprofit and patient-focused**.

CRITICAL PATH INSTITUTE 20 YEARS OF IMPACT

Powered by C-Path: a nonprofit that for two decades has united scientists, regulators, and industry to **accelerate safe, effective treatments to patients.**

C-Path's Public-Private Partnership Model

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1. Foster development of new evaluation tools to inform medical product development and regulatory decision-making
2. Convene scientific consortia of industry, academia, and government for sharing of data/expertise

Active consensus building → **Shared risk and costs** → **The best science** → **The broadest experience**

3. Enable iterative EMA/FDA/PMDA participation in developing new methods to assess the safety and efficacy of medical products
4. Obtain official regulatory endorsement of novel methodologies and drug development tools

C-Path Precompetitive Neutral Ground

- Industry Partners
- Regulators
- Patient Groups
- Academia

Far-Reaching Impact

40 formal regulatory accolades

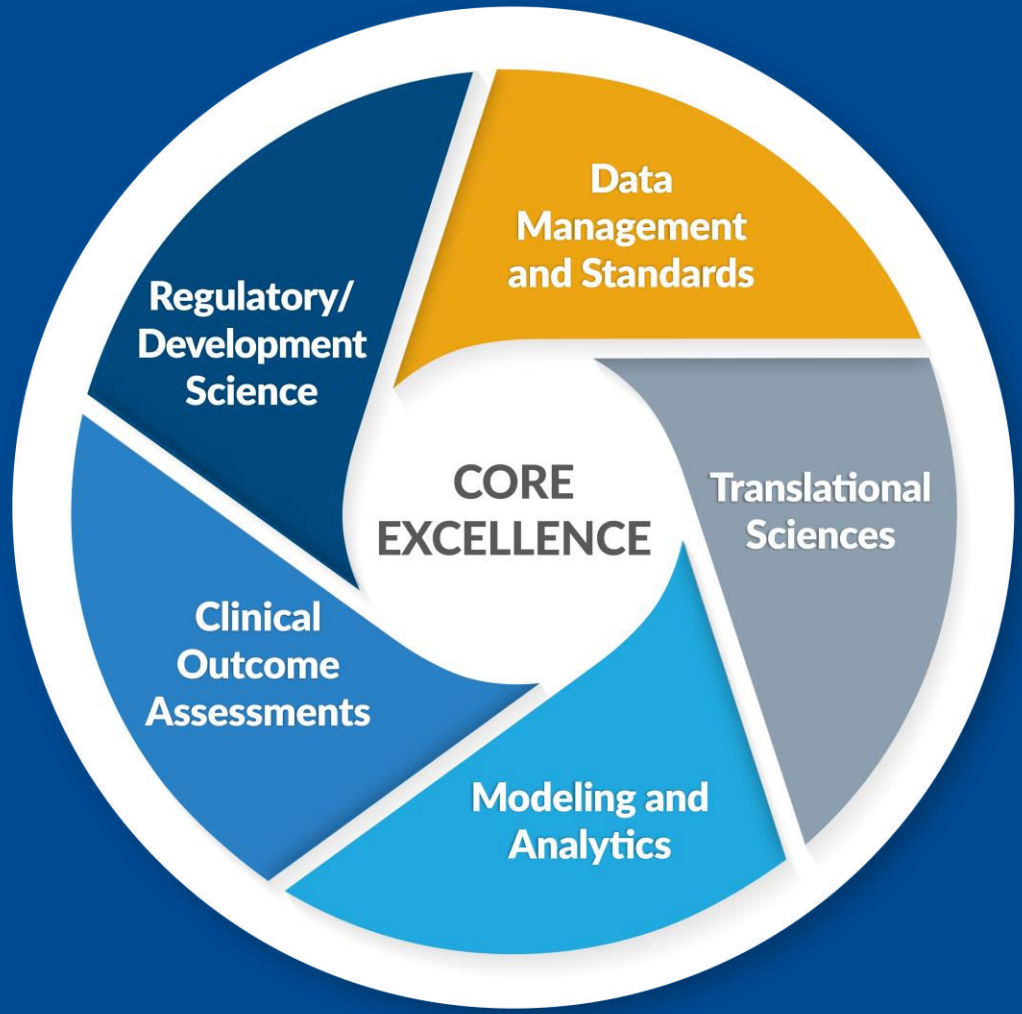
1,600+ science and data contributors

400+ strategic partnerships organizations

$40M+ annual budget

24 active programs

1,100+ peer-reviewed publications



How TRxA Operates within the C-Path Context

TRxA synergizes with C-Path's >20 consortia

- Consortia are focused on drug development tools (DDTs) and their regulatory endorsement and TRxA focuses on development of drugs, but…:
- Consortia provide access to subject matter expertise

TRxA applies C-Path's expertise to move projects towards the clinic, as fast as possible

Our Scope

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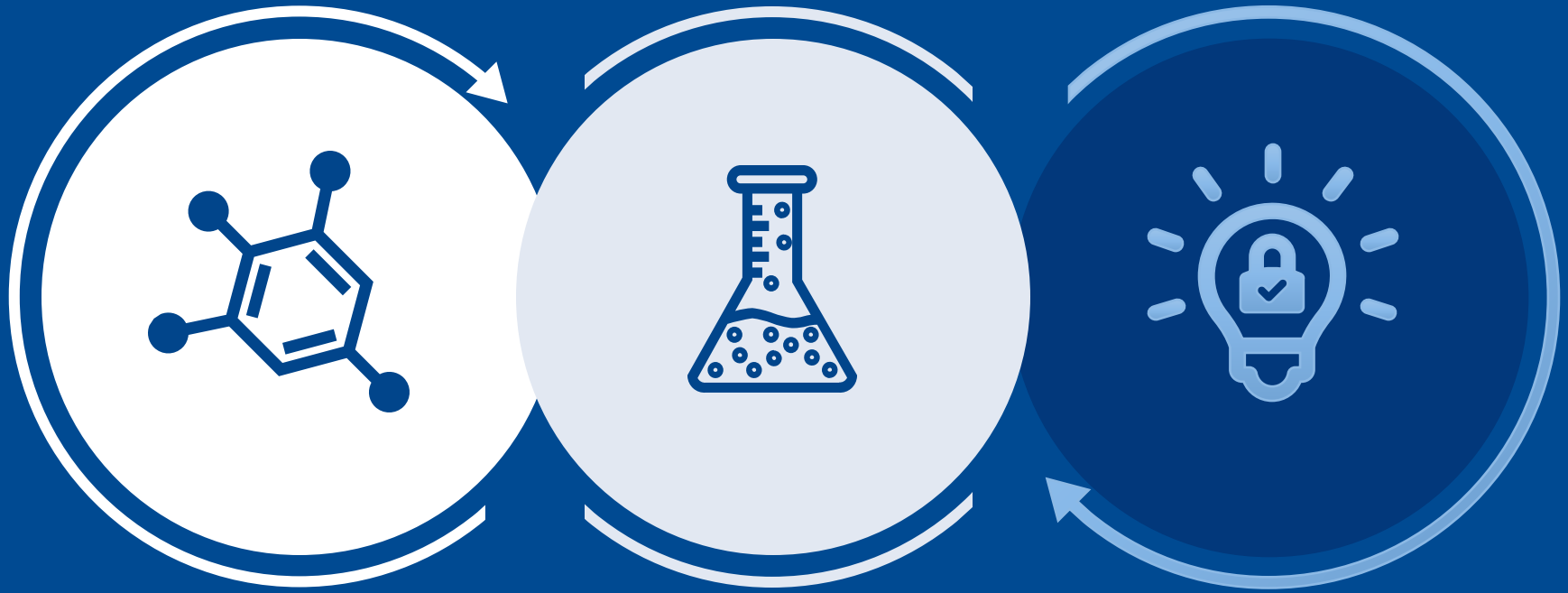

Therapeutic Molecules
in lead optimization/IND enabling studies

Composition of Matter
IP in place or obtainable

Intellectual Property
still within the institution

Frederick Gartner Cottrell Foundation

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Research Corporation Technologies established the **Frederick Gardner Cottrell Foundation** in December 1998 to provide financial support for scientific research and educational programs at qualified nonprofit organizations.

Translational Therapeutics Accelerator Model

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How it begins

- Launch disease-focused RFPs
- Align with funder priorities and investment
- Build global pipeline of academic discoveries
- Awards vary based on maturity and range from USD $250,000 to $1,000,000

How we drive it

- Expert reviews & due diligence
- Milestone-based awards with go/no-go gates
- Hands-on support: scientific, translational, and regulatory
- Stimulate early industry feedback loops
- IP remains with awardees

What it delivers

- Focus on drug development; reduced emphasis on traditional academic outcomes
- Investor-ready “data packages”
- Increased success for follow-on funding / licensing pathways
- Higher likelihood of reaching the clinic

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TRxA BRIDGe Awards

C-Path's Translational Therapeutics Accelerator Bridging Research and Innovation in Drug Development Grants

Including a dedicated Polycystic Kidney Disease track

PKD FOUNDATION
Polycystic Kidney Disease

c-path.org

BRIDGe Awards 2026

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Indications
Rare and Orphan Diseases*
Brain Health**
Pediatric Indications
Polycystic Kidney Disease

Modalities
Small Molecules
Protein-based Therapeutics
In Vivo Gene Therapies

** Co-funding opportunities with Project CASK*

*** Co-funding opportunities with Cerebrum DAO*

BRIDGe Award Amounts

Early lead molecules to late lead series

Up to **$250,000**

Late lead series to selection of clinical candidate

Up to **$500,000**

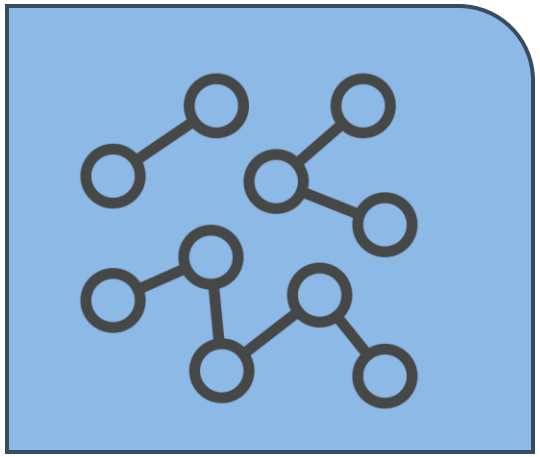
Candidate selection through IND enabling studies

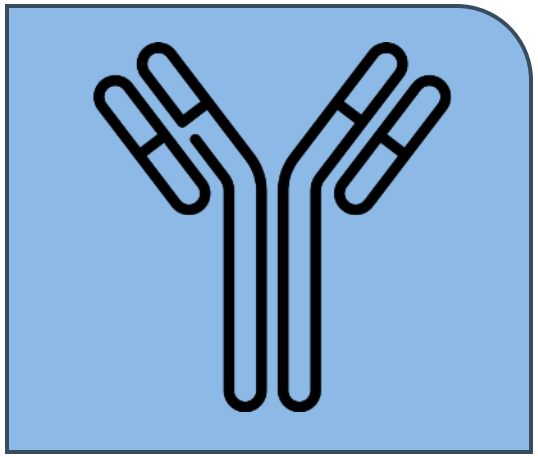
Up to **$1,000,000**

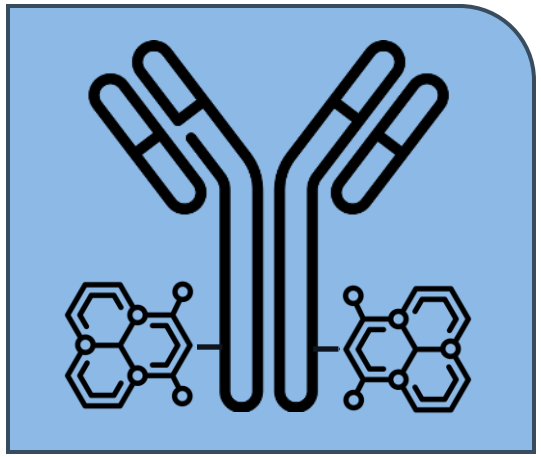
Protein-Based Therapeutics

Examples:

- Peptides or proteins
- Regular, bi-valent or tri-valent antibodies
- Antibody-drug conjugates, Protein-drug conjugates



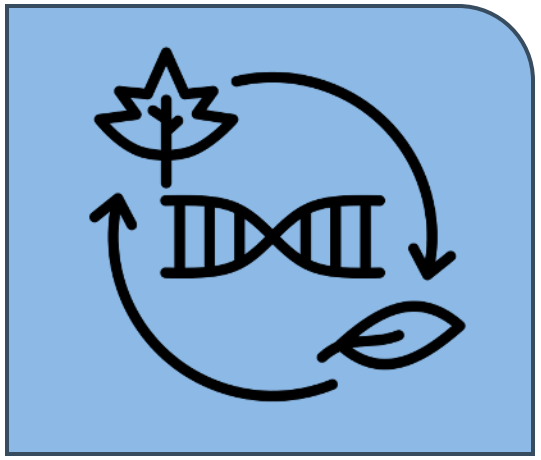


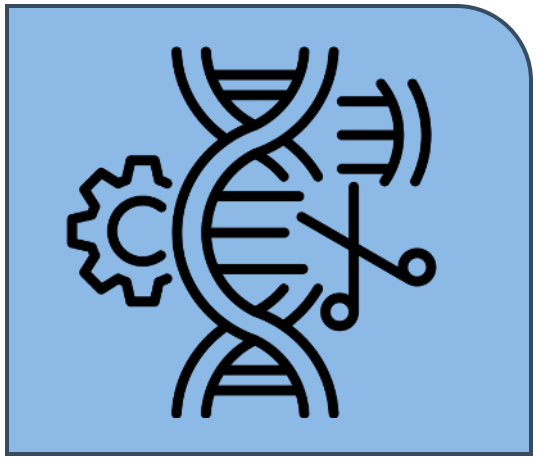


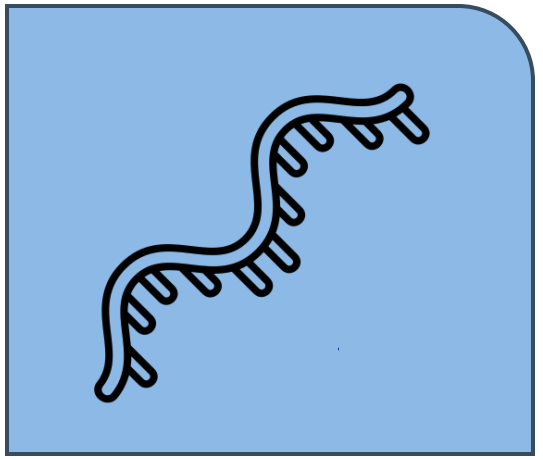
In Vivo Gene Therapies

Examples:

- Gene replacement (for example, using the liver as a factory)
- In vivo gene editing
- Gene silencing
- Oligonucleotides







Eligibility Criteria – BRIDGe Awards

Small Molecule – Stage 1	
✓	A compound progression pathway has been established with clear criteria
✓	A target product profile has been completed
✓	The project is in early lead optimization
✓	There is demonstrated optimizable Structure-Activity-Relationship
✓	In vitro assays are in place, with appropriate throughput
✓	In vivo models are available; no need to have animal data (but encouraged)
✓	IP is in place or obtainable

Eligibility Criteria – BRIDGe Awards

Small Molecule – Stage 2	
✓	A compound progression pathway has been established with clear criteria
✓	A target product profile has been completed
✓	A lead series is in place with characterized in vitro pharmacology properties, including cell-based activity and ADME.
✓	Optimized candidates from (preferably) multiple series are available, with remaining optimization goals identified.
✓	The lead series has shown target engagement in vivo

Eligibility Criteria – BRIDGe Awards

Small Molecule – Stage 3
✓ A target product profile has been completed
✓ A clinical candidate has been selected, with characterized ADME properties and shown efficacy in an in vivo model.
✓ The clinical candidate has characterized toxicology properties
✓ A GMP scale-up and characterization plan is in place
✓ A non-clinical formulation has been defined

Eligibility Criteria – BRIDGe Awards

Protein-based Therapeutics – Stage 1	
✓	A candidate progression pathway has been established with clear criteria
✓	A target product profile has been completed
✓	The project is in lead optimization
✓	In vitro assays are in place, with appropriate throughput
✓	Immunogenicity potential has been assessed; derisking strategy identified
✓	Target engagement in vivo has been demonstrated
✓	IP is in place or obtainable

Eligibility Criteria – BRIDGe Awards

Protein-based Therapeutics – Stage 2	
✓	A candidate progression pathway has been established with clear criteria
✓	A target product profile has been completed
✓	One or more (humanized) PBT molecules have been profiled so that further optimization needs have been clearly defined
✓	A strategy to reduce immunogenicity is in place
✓	Therapeutic efficacy in vivo has been demonstrated
✓	Small scale manufacturing is available; cGMP manufacturing and scale up are feasible
✓	Enabling technologies for delivery or manufacturing are available, not blocked by exclusive IP

Eligibility Criteria – BRIDGe Awards

Protein-based Therapeutics – Stage 3	
✓	A candidate progression pathway has been established with clear criteria
✓	A target product profile has been completed
✓	A clinical candidate has been selected, with characterized ADME properties and shown efficacy in an in vivo model.
✓	The clinical candidate has characterized toxicology properties
✓	A GMP scale-up and characterization plan is in place
✓	A non-clinical formulation has been defined

Eligibility Criteria – BRIDGe Awards

In Vivo Gene Therapies – Stage 1	
✓	A target product profile has been completed
✓	The vector only targets somatic cells and avoids the germline; projects must use a delivery platform with a clinical track record
✓	The target tissue and delivery route are well-defined; in vivo efficacy has been demonstrated
✓	For vector-based therapies, the promotor/enhancer results in tissue-appropriate expression; assays are in hand to determine capsid quantification
✓	For oligo-based therapies, SAR should be demonstrated, with assays available and validated
✓	Toxicity and immunogenicity potential has been assessed; derisking strategy identified
✓	Small scale manufacturing is available; cGMP manufacturing and scale up are feasible
✓	IP is in place or obtainable; enabling technologies for delivery or manufacturing are available, not blocked by exclusive IP

Eligibility Criteria – BRIDGe Awards

In Vivo Gene Therapies – Stage 2	
✓	Small scale production of preclinical grade material is complete; scale up hurdles are addressed
✓	Biodistribution has been evaluated in a relevant animal model
✓	Preliminary maximum feasible dose and dose-response relationship has been established
✓	Expression has been confirmed via fluorescence, qPCR or immunohistochemistry
✓	Integration or insertion-site analysis has been initiated to assess profile and risk
✓	Demonstrated functional rescue of phenotype
✓	Preclinical safety program planned including assessments of tox, immunogenicity, etc.
✓	Clear clinical plan with potential biomarkers and endpoints identified

Eligibility Criteria – BRIDGe Awards

In Vivo Gene Therapies – Stage 3	
✓	For vector-based therapies, scale up and batch consistency has been demonstrated across ≥3 lots
✓	Stability studies demonstrate adequate shelf-life for clinical use
✓	Minimal immune activation at clinical dose
✓	NOAEL established with no systemic tox demonstrated in appropriate species
✓	Critical quality attributes (CQAs), critical process parameters (CPPs) and release specifications for GMP manufacturing have been defined

3-Step BRIDGe Project Selection Process

1. Call for Pre-proposals (SF grants portal; deadline Monday March 16)

   High level description, non-confidential summary information about the project, such as the biological target and project goals

   Reviewed by TRxA's 'Programmatic Review Board' (PRB) and the PKDF to determine which projects advance in the process

2. Request for CDAs (request sent by May 15; deadline June 17)

   Initiate and finalize CDAs with institutions selected to advance in the process

   Secure repository made available to upload any confidential information (e.g., chemical structures if using a small molecule, data package around lead)

3. Invitation for full proposals (invitations by July 1; deadline August 12)

   Coaching and mentoring provided by the TRxA team to put together a plan

   Reviewed by a standing 'Scientific Advisory Committee' who will score the proposals

   Scores forwarded to PRB/PKDF, who make the final selection of funding

TRxA Support

- Funding…
- Monthly project team meetings with bespoke team member composition from
  - TRxA and the larger C-Path organization
  - PKD Foundation scientific and disease experts (for PKD track projects)
- Feedback and advice from our Scientific Advisory Committee (upon project selection, halfway, and at the end of the project)
- Connections to needed external services or expertise

FAQs

Who We Fund

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Who is eligible for TRxA funding?

- **Faculty at universities and non-profit institutions, anywhere around the world.**

Who We Fund

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Are there any institutional commitments required, if funded?

- **Institutions will be expected to engage with TRxA and negotiate a reasonable project agreement commensurate with the funding provided. A template of this agreement is available on our website.**

What We Fund

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What therapeutic areas are eligible for TRxA BRIDGe awards?

- **Rare and orphan diseases**
- **Brain health**
- **Pediatrics**
- **Polycystic Kidney Disease (dedicated PKDF track)**

What We Fund

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Do you have criteria for what qualifies for the in vivo gene therapy modality, beyond the examples you gave?

- **Projects must use a delivery platform with a clinical track record**
- **Excluded:**
  - **Exosomes as delivery vehicles**
  - **Replication competent viral vectors (such as Ad, VSV, HSV, etc.)**
  - **Targeting germline cells**

How Funding Works

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Are indirect costs/overhead allowed?

- **IDC is limited to 10%, with passthrough costs to service providers not eligible for IDCs.**

How Funding Works

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Does TRxA funding all come to my lab?

- **Funds are awarded to the project, not necessarily the PI's laboratory; part (or most) of the funds may, for example, go to CROs or consultants.**

How Funding Works

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What are allowable costs?

- **Costs associated with defined project tasks, such as lab supplies, animal procurement, salaries or core services. Not allowed are general lab expenses, travel, equipment, tuition or IP prosecution and maintenance costs.**

How Funding Works

Do I need to worry about having other funding sources for my projects?

- **No, in fact TRxA likes to partner with other funders, to accelerate your project**
  - **Examples of co-funding partners for 2026 include Project CASK and Cerebrum DAO**

CROs & IP

How do I find the right CRO, if I need one?

- **If you require advice, TRxA can help identify suitable CROs for (part of) the work; we have no geographic restrictions. Management of the contract will be through your institution, but the TRxA team is happy to help manage the work to be done.**

CROs & IP

Do I need quotes for my (pre-)proposal?

- **You do not need quotes for early-stage work, and TRxA can provide some ballpark numbers for standard drug discovery assays such as selectivity panels or PK studies to help you build your budget. For later stage work, if a large portion of funding will go to a CRO, a quote may be needed.**

CROs & IP

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Do I need to have IP filed on my compound before applying?

- **No, there is no requirement that IP protection is in place, rather that the composition of matter is eligible for protection. We do expect IP will be filed internationally.**

Application Process

How do I apply?

- **Create an account in TRxA's grant portal on the Salesforce platform; links can be found on the TRxA website at https://c-path.org/programs/trxa/**
- **The portal will automatically close at midnight in your local time zone on the date of the deadline (March 16), so please start early to mitigate any technical submission issues.**

Application Process

How many projects do you fund?

- **We anticipate funding 3-5 awards this funding cycle. There is no pre-determined number of awards in certain therapeutic areas, modality, or funding level.**

Application Process

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What is the chance of success for my application?

- **Although it may differ from cycle to cycle, for 2025, we received a total of 79 pre-proposals, 20 full proposals (25%) were submitted and 5 were funded (25%)**

Application Process

Can I get advice on my application? I have questions!

- **The TRxA team is available for questions via email at trxa@c-path.org**

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Next Steps:

1. Create an account in the Salesforce grant portal via https://c-path.org/programs/trxa/
2. Submit your proposal by 16MAR2026 (start early!)