TRxA
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Critical Path Institute's Translational Therapeutics Accelerator

FUNDING OPPORTUNITY FOR DRUG DISCOVERY AND DEVELOPMENT

Guidance for Applicants

BRIDGe

- Bridging
- Research and
- Innovation in
- Drug Development
- Grants

Introduction

Critical Path Institute's (C-Path) Translational Therapeutics Accelerator (TRxA) is proud to announce its 2024 global Request for Proposals for its Breakthrough Research and Innovation in Drug Development Grants (BRIDGe). These BRIDGe awards are designed to support academic researchers in traversing the drug development valley of death by funding and defining optimal strategies for advancing new, cutting-edge therapeutics from the lab to patients.

The following elements of this document will assist interested applicants in learning more about TRxA BRIDGe awards and understanding what is required to apply for funding and support through this unique drug accelerator program.

- About C-Path and TRxA
- Types of Projects Eligible for Funding
- Types of TRxA BRIDGe Awards
- The Application Process and Award Notifications
- Pre-Submission Considerations and Consultations
- Scientific Review Process and Review Criteria

About C-Path and TRxA

C-Path is a non-profit that leads collaborations to accelerate drug development and advance better treatments for people worldwide. As a neutral convener of patient groups, academia, pharmaceutical companies and regulatory agencies, C-Path brings a breadth of scientific and drug development planning not available in other drug development accelerators. TRxA is uniquely positioned to leverage the expertise available through C-Path's >20 disease-based consortia, as well as regulatory expertise and project management, to empower your program and your institution to succeed.

TRxA operates as a global not-for-profit drug accelerator that provides funding to academic researchers, as well as:

- Tactical and strategic drug discovery and development expertise, including regulatory science considerations.
- Resources and hands on guidance, working closely with researchers to develop comprehensive data packages for potential drug candidates, a key to garnering interest from biotechnology and pharmaceutical companies to invest in clinical trials.
- Engagement of contract research organizations (CROs) to perform critical discovery phase experiments and/or validate academic studies.

Intellectual property (IP) remains solely the property of the principal investigator's (PI) institution. In the event that TRxA is a co-inventor to any technology related to the project, the PI's institution shall wholly own assignment to the invention. C-Path does not take any ownership in generated IP.

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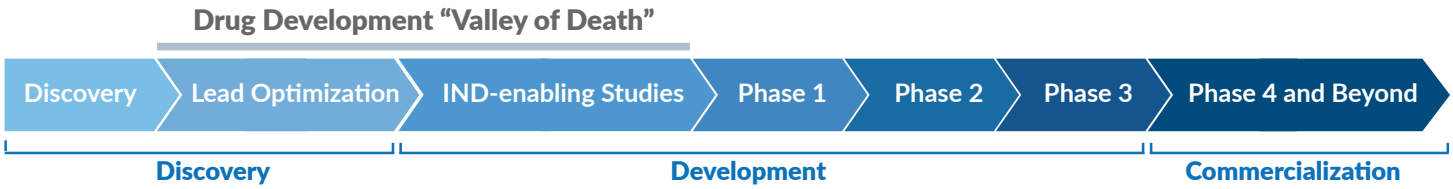
C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world.

Types of Projects Eligible for BRIDGe Awards

Projects eligible for TRxA BRIDGe awards include early lead optimization and IND-enabling studies, using small molecule approaches, anywhere in the world. Biologicals, including peptides or antibodies, oligonucleotides, cell and gene therapy applications and medical devices are not eligible at this time. Drug repurposing approaches are also not eligible during this funding cycle.



TRxA is a disease and target agnostic funder and has no geographical restrictions for grantees, although applicants must be faculty members at a university or non-profit research institution. Ownership rights to the program must reside at a university or not-for-profit research institution. An option or agreement to an exclusive license cannot be in place at the time of funding.

Types of TRxA BRIDGe Awards

TRxA offers funding and support for three types of small molecule translational projects, ranging from early lead optimization to IND-enabling studies. Available funding levels are as follows. Entry criteria for each stage of funding are provided in Exhibit A.

STAGE 1

Early lead compound to late lead series

Funding up to $250,000 for approximately 1 year

STAGE 2

Late lead series to selection of clinical candidate

Funding up to $500,000 for approximately 1 year

STAGE 3

Candidate selection through IND enabling studies

Funding up to $1,000,000 for approximately 1 year

The Application Process and Award Notifications

STEP 1: The principal investigator (or co-PIs) will submit a non-confidential pre-proposal that will be reviewed by C-Path's scientific experts and TRxA's Programmatic Review Board (PRB), which has broad expertise in drug discovery and development. Details about elements required in pre-proposals are provided in Exhibit B. Applicants are also encouraged to review the sample pre-proposal here.

After review, TRxA will invite selected projects for the next step in the process. Due to volume, no formal reviewer feedback will be provided to applicants at this stage, although the TRxA team will make an effort to convey any particular items of concern that were brought up during the PRB's discussions.

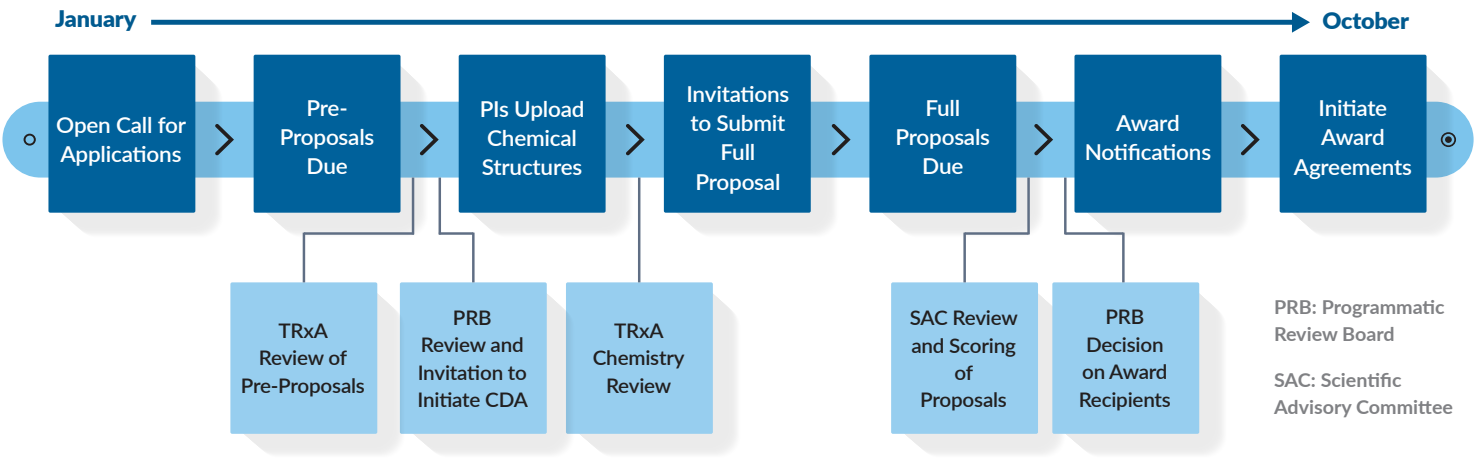
It is recommended that applicants coordinate with their university's tech transfer and/or grants and contracts office in advance of the submission to provide an opportunity for review of the TRxA award agreement template to ensure the terms would, in principle, be acceptable.

Prior to submission of the pre-proposal, the TRxA team is available to meet with PIs via email or teleconference to answer any questions about pre-proposal requirements, the award process, or to seek feedback on how to optimize your submission. If a teleconference is desired, these 30-minute consults will be available on a first come-first served basis until March 22, 2024 and can be requested via email to TRxA@c-path.org, after which the requester will be directed to a form that collects pertinent information, to make the consult as effective as possible.

To start building your pre-proposal, click here for access to TRxA's grant portal. You will be asked to set up a username and password before starting the pre-proposal application (click here to access the grant portal User Guide). If you encounter any technical issues with the portal, please email us at TRxA@c-path.org.

The deadline for submitting a pre-proposal through the portal is **March 31, 2024** by midnight in the time zone in which you are located. It is recommended that you set up your username and password at least one week prior to this submission deadline to allow sufficient time for troubleshooting in the event you experience any technical difficulties.

Notifications about whether applicants have been invited to advance to Step 2 of the application process will be issued the week of **May 13, 2024**.



STEP 2: Selected applicants will be invited to enter into a confidentiality agreement (CDA) with C-Path, after which the applicant will upload information about the chemical structure of the lead molecule(s) to the grant portal using a fillable PDF document that will be supplied. The TRxA team along with experienced medicinal chemists will review the submitted structures to further select which applications move to Step 3, where applicants are invited to submit a full proposal.

STEP 3: PIs who are invited to submit a full proposal will be notified via email by July 3, 2024. The deadline for full proposals is August 26, 2024. Optional pre-submission consultations with the TRxA team will be available to PIs to answer questions and optimize the proposal and related materials between July 8 and August 16, 2024.

Required content for full proposals is provided in Exhibit C. Full proposals will also be submitted through TRxA's grant portal. There may be overlap in questions from the pre-proposal to the full proposal; it is sufficient to repeat information already supplied as the external scientific advisors will not have access to your pre-proposal submission. You can also view our example full proposal for additional insights into what is being requested.

Pre-submission Considerations and Consultations

If not done so at the pre-proposal stage, at this time it is required that you coordinate with your university's tech transfer and/or grants and contracts office in advance of your submission(s) to:

1. Make them aware that you have been invited to submit a full proposal,
2. Provide an opportunity for review of the TRxA award agreement template to ensure the terms would, in principle, be acceptable and,
3. Request a letter of support, which will be needed at the time of full proposal submission.

You will note that the award agreement includes TRxA operational policies and procedures, which are also provided in this document as Exhibit D.

Once again, during this process, the TRxA team is available to communicate via email or meet via teleconference to answer any questions about proposal requirements, the award process, or to seek feedback on how to optimize your submission. These optional consultations are available on a first come, first served basis and can be requested via email to TRxA@c-path.org. Pre-proposal consultations are available until March 22, 2024. Full proposal consultations are available from July 8 to August 16, 2024.

Note: If requesting feedback on your pre-proposal or full proposal, you will be asked to declare specific questions in advance and submit a draft at least 2 business days prior to your scheduled meeting.

Scientific Review Process and Review Criteria

Proposals will be reviewed by at least three external scientific advisors and scored for novelty, scientific and technical merit, as well as commercialization potential. A list of these scientific advisors can be found here. TRxA will select up to six proposals to fund, based on results of the reviews and requested funds as well as programmatic fit. Award notifications will be issued the week of October 14, 2024. All proposals will be evaluated based on the following criteria:

The project addresses an unmet medical need: The novel drug substance should address a significant unmet need and, once approved, will offer a new or significantly improved medical solution for patients.

Novelty: The target, mechanism, or mode of action should have sufficient novelty to be differentiating from approaches already in the marketplace or in the pipeline of biotech and pharmaceutical industries.

Commercial viability: Assuming the project is successful, there should be potential to generate interest from industry partners or venture capital groups to further develop the project, based around market positioning and potential, as well as intellectual property (IP) status. Of note, it is expected that broad international protection of composition of matter IP has been or can be obtained.

Sound scientific rationale for the target: The project should be based upon sound scientific evidence, such as data supporting the validity of the target and the approach generated by the PI or from peer-reviewed scientific publications. Any predictable liabilities for either the target or the compound series are being addressed in the project plan.

Well-structured, quality project plan: The project should be designed to facilitate meaningful outcomes to support the next stage in the drug development process. Timelines should be realistic, with achievable deliverables clearly articulated. Risk and mitigation strategies should have been identified. Potential clinical approaches have been identified, along with needed biomarkers and endpoints.

Likelihood of success: What is the likelihood that the project will reach its key inflection point, based on the project plan, available resources and the investigative team? The investigators should be well positioned to successfully implement the research plan, especially when working in collaboration with the TRxA team, collaborators and associated CROs. The resources needed to conduct activities should be in place to achieve the proposed deliverables.

Budget justification: The proposed timeline and budget should be appropriate and realistic. Scheduling of CRO work product should fit within the period of funding.

Overall enthusiasm: Taking the aspects above into account, what is the overall enthusiasm for the proposed project?

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Critical Path Institute (C-Path) is an independent, nonprofit established in 2005 as a public-private partnership, in response to the FDA's Critical Path Initiative. C-Path's mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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EXHIBIT A

Entry and Success Criteria for BRIDGe Awards

STAGE 1 PROJECTS

ENTRY CRITERIA

- Project is in early lead optimization
- Tractable drug leads from multiple chemical series have been identified (demonstration of optimizable SAR)
- Established *in vitro* pharmacology assays (biochemical and cell-based potency and selectivity)
- Access to an available or conceived *in vivo* pharmacodynamic model

SUCCESS CRITERIA

- Well-defined compound progression pathway with established success criteria
- Optimized leads from multiple series
  - Characterized *in vitro* pharmacology properties including cell-based activity
  - Characterized ADME properties (*in vitro* and rodent *in vivo*)
  - Demonstrated *in vivo* pharmacology in pharmacodynamic model
- Access to an available or conceived *in vivo* pharmacodynamic model

STAGE 2 PROJECTS

ENTRY CRITERIA

- Well-defined compound progression pathway with established success criteria
- Optimized leads from multiple series
  - Characterized *in vitro* pharmacology properties including cell-based activity
  - Characterized ADME properties (*in vitro* and rodent *in vivo*)
  - Demonstrated *in vivo* pharmacology in pharmacodynamic model
- Access to an available or conceived *in vivo* pharmacodynamic model

SUCCESS CRITERIA

- Defined target product profile (TPP) and vetted regulatory plan to achieve the TPP
- Optimized molecule meeting candidate selection success criteria
  - Characterized *in vitro* and *in vivo* pharmacology including demonstrated efficacy in an *in vivo* efficacy model
  - Characterized ADME properties (*in vitro* and rodent/non-rodent *in vivo*)
  - Characterized toxicology properties (*in vitro* and rodent/non rodent *in vivo*)
  - Defined non-clinical formulation
- Defined API scale up and characterization plan

STAGE 3 PROJECTS

ENTRY CRITERIA

- Defined target product profile (TPP) and vetted regulatory plan to achieve the TPP
- Optimized molecule meeting candidate selection success criteria
  - Characterized *in vitro* and *in vivo* pharmacology including demonstrated efficacy in an *in vivo* efficacy model
  - Characterized ADME properties (*in vitro* and rodent/non-rodent *in vivo*)
  - Characterized toxicology properties (*in vitro* and rodent/non rodent *in vivo*)
  - Defined non-clinical formulation
- Defined GMP API scale up and characterization plan

SUCCESS CRITERIA

- Adherence to the TPP and regulatory plan
- Well characterized molecule with complete toxicology package to enable FIH study
  - General toxicology
  - Safety toxicology
  - Genetic toxicology
- Optimized GMP API scale up strategy

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EXHIBIT B

Required Elements of Pre-proposal Submissions

Pre-proposal applications will be submitted through TRxA's grant portal. It is recommended that pre-proposals be created as a Word document, then cut and pasted into appropriate fields in the online application.

1. **Project title**

2. **Names, contact information, and brief background** *(1000 characters maximum)* **of principal investigator(s) that highlights expertise available to the proposed project.**

3. **Names and contact information for co-investigators within or outside your institution, as well as a brief explanation** *(1000 characters maximum)* **about the reason for the collaboration and the expertise of those listed.**

4. **Name and email of Technology Transfer Office Rep**

5. **Name and email of Award Notification Recipient**

6. **Type of BRIDGe award being requested (Stage 1, 2 or 3)**

7. **Total funding being requested (in USD)**

8. **Please provide a non-confidential project abstract.** This non-confidential information may be shared with external reviewers and potential co-funders *(2200 characters maximum)***.**

9. **What is the therapeutic indication and the target population of this new drug product** *(375 characters maximum)*?

10. **What is the biological target and/or pathway of the compound(s)** *(260 characters maximum)*?

11. **Is there structural information for the target?** If yes, please describe. *(1500 characters maximum)*.

12. **How does this project address an unmet medical need** *(450 characters maximum)*?

13. **Describe the novelty of the project's approach.** If there are marketed products available for the stated indication, or if similar research is being done in this area by competitors, what differentiates this project *(1000 characters maximum)*?

14. **Is there genetic evidence of the relevance of your target in the therapeutic indication you propose?** For example, are there naturally occurring mutations in humans that illustrate the role this target plays in the disease *(1000 characters maximum)*?

15. **What scientific rationale, in addition to any genetic evidence mentioned earlier in this pre-proposal, is in place that manipulation of this target results in amelioration of disease?** *(2000 characters maximum)***?** Please provide figures as appropriate; figures must be readable as printed on a single 8.5" x 11" page at normal 100% scale, so please ensure appropriate resolution. If appropriate, upload this one page with up to four (4) figures to illustrate scientific concepts and findings.

16. **Is there a validated biomarker or clinical assessment available that can be used in human trials and/or preclinical animal experiments that is reasonably likely to predict clinical outcome?** If yes, please describe. *(1500 characters maximum)*

17. **Are there any predictable safety issues that need to be considered in light of the target, anticipated dosing regimen and/or any liabilities of the compound(s)** *(450 characters maximum)*?

18. **What is the status of any IP associated with this project and this compound/compound series?** Provide patent or application numbers if published *(1500 characters maximum)*

19. **What are the next steps needed to drive the project towards IND and/or commercial interest of potential licensing partners** *(1500 characters maximum)*?

20. **List and describe activities to be performed with the funding requested, in light of the needed next steps mentioned above.** Per activity, indicate availability of assays/technology needed to evaluate compounds, location of the work to be performed (at your institution, a collaborator, or a CRO), anticipated timeline and funds needed to complete the work package. *(3300 characters maximum).*

21. **If applicable, list funding already secured related to the project that would complement TRxA support** (e.g., grants, institutional funds). *(1000 characters maximum).*

22. **References** *(10 000 characters maximum).*

23. **List of abbreviations** *(2000 characters maximum).*

File uploads: Optional onepage attachment, saved as scientificrationale.pdf

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EXHIBIT C

Required Elements of Full Proposal

The following elements of your full proposal, and associated maximum character counts, are provided below.

I. Applicant Information and Requested Grant Amount

- ☐ **Name of principal investigator and co-investigator(s). Include email addresses**
- ☐ **Requested funding amount. US dollars only**
- ☐ **Name of institution.**
- ☐ **Institution's tax ID number.**
- ☐ **Institution's address.**
- ☐ **Name and email address of Tech Transfer Office liaison.** Note: A Letter of Support from the TTO or equivalent should also be provided as an attachment. Save attachment as "LetterofSupport.pdf"
- ☐ **Name and email address of Award Notification Representative.**

II. Project Overview

Provide an overview of the project, its objectives, and the potential achievable results. The logic underlying the scientific hypothesis should be clearly described, along with a clear explanation of why the proposed work is an efficient and effective way to support the hypothesis. Provide a definition of research specific abbreviations, acronyms, or symbols embedded once throughout the text.

1. **Project title.** *255 characters or less/approx. 30 words or less*
2. **Therapeutic indication & population.** *255 characters or less/approx. 30 words or less*
3. **Biological target and/or pathway.** *255 characters or less/approx. 30 words or less*
4. **Non-confidential project summary.** *1500 characters or less/approx. 200 words or less*
5. **How does this project address an unmet medical need.** *750 characters or less/approx. 100 words or less*
6. **If there are marketed products available for the stated indication, or if similar research is being done in this area by competitors, what differentiates this project?** *1000 characters or less/approx. 150 words or less*
7. **Describe the status of any IP associated with this project and this compound/compound series.** *1650 characters or less/approx. 250 words or less*
8. **Describe any industry engagement, if any.** *1000 characters or less/approx. 150 words or less*

9. **What scientific rationale, in addition to any genetic evidence, is in place that manipulation of this target results in amelioration of disease?** *5000 characters or less/approx. 750 words or less* and optional 1 page attachment (letter size) with legible figures, save attachment as "Scientific_Rational.pdf"

10. **Describe the novelty of the project's approach.** *3300 characters or less/approx. 500 words or less* and optional 1 page attachment (letter size) with legible figures, save attachment as "Novelty.pdf"

11. **Describe available or conceived in-vivo models and prediction of translation to human subjects.** *2300 characters or less/approx. 350 words or less*

12. **Provide a statement, if applicable, explaining how the study conforms to appropriate ethical regulations and guidelines regarding the use of animals in research.** Include the name of the institution where the research was approved and the ethics committee that reviewed it. *750 characters or less/approx. 100 words or less*

13. **Describe the biomarker(s) and the theoretical or empirical basis for their potential utility. Biomarkers may reference levels of analytes in fluids/samples, radiologically measured parameters, event time frames, or any other objectively measured values used to reach a single interpretation.** Specify the aspect of the marker that is measured and the form in which it is used for biological interpretation. *1600 characters or less/approx. 250 words or less*

14. **Are there any predictable safety issues that need to be considered in light of the target, anticipated dosing regimen and/or any liabilities of the compound(s)?** *1650 characters or less/approx. 250 words or less*

15. **Replication of key experiment(s): Reproducibility is key for garnering interest of future investors or licensees;** if not done already, please describe which key experiment(s) should be repeated by a neutral third party at the start of this program, to increase confidence of the robustness of your observations. *1000 characters or less/approx. 150 words or less*

III. Project Readiness

16. **List the activities to be performed to drive the project towards IND and/or commercial interest and describe study design, methods, models, and analyses in sufficient detail for assessment of the application.** *5000 characters or less/approx. 750 words or less* and optional 1 page attachment (letter size) with legible figures, save attachment as "Key_Activities.pdf"

17. **Describe the availability and access to structure-based optimization: co-crystal structures, homology models.** *1650 characters or less/approx. 250 words or less* and optional 1 page attachment (letter size) with legible figures, save attachment as "Structural_Models.pdf"

18. **Describe tiered screening and how compounds will be evaluated, 'go' & 'no-go' decision points.** Describe the tiered screening process on how compounds will be evaluated, order of assays and 'go' and 'no-go' decision points/values. *3300 characters or less/approx. 500 words or less* and required 1 page attachment (letter size) with legible figures, save attachment as "Tiered_Screening.pdf"

IV. Goals and Objectives

19. **Provide a Gantt chart of expected project plan covering period of the funding.** Required 1 page attachment (letter size) with legible figures, save attachment as "Gantt.pdf"

20. **Outline the current chemical synthetic pathways and describe feasible modifications to address identified issues or SAR expansion around the lead compound(s).** *4500 characters or less/approx. 700 words or less* and optional 1 page attachment (letter size) with legible figures, save attachment as "Chemistry.pdf"

21. **Describe work that will be done in research collaborators' labs and work that will be carried out in CROs.** *750 characters or less/approx. 100 words or less*

22. **What are the known on-/off-target associated risks and mitigation strategy.** *3300 characters or less/approx* and optional 1 page attachment (letter size) with legible figures, save attachment as "Risks.pdf"

23. **Describe how the proposed validation approaches or corroborative studies reduce the risk that the findings from the animal study cannot be translated into human populations.** Include a discussion of the degree of homology between the animal and human target(s), pertinent to interaction with the compound, as well as translatability of animal models to the human condition. *1500 characters or less/approx. 200 words or less*

24. **Project team: Provide a brief background of each PI and co-PI's expertise as related to this proposal.** *1500 characters or less /approx. 200 words or less*

25. **Budget and budget justification.** Using the template provided in the grant application portal, include a detailed project budget that outlines total requested funds for all activities.

26. **Bibliography & references cited.** Can be provided as an attachment, if preferred save attachment as "Bibliography.pdf"

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EXHIBIT D

TRxA Operational Policies and Procedures

The following describes policies and procedures that inform TRxA grant operations with respect to, among others, decision making, publications, grant and patent applications and the adjudication process(es); recognizing that the formal legal agreement is the ultimate governing document.

Scientific decision making and planning of experiments

Scientific direction of the project is governed by the university's Principal Investigator(s) (PI(s)) together with TRxA personnel (Executive Director and the Director of Drug Discovery and Development). This project team will decide on the order of experiments, based on the team members' expertise and input from external consultants, as appropriate. The team will also define target values for the lead molecule(s) and define go/no-go decision-making points in the project. TRxA reserves the right to either stop funding the project if progress has not been sufficiently made, or, alternatively, increase the amount of funding available for the project if warranted.

Intellectual property protection and publication of results

Decision making around protection of IP

Care should be taken to not jeopardize the intellectual property (IP) being developed, with support from TRxA, by publishing prior to appropriate protection being in place. Such protection should be sufficient to garner and maintain the interest of biotech and pharma for potential licensing of the IP (ideally worldwide protection, or at minimum the US and EU). The project team will try to achieve consensus on the best IP strategy. However, since IP is owned by the academic institution, their respective tech transfer and/or licensing office is ultimately responsible for making these patent protection decisions. TRxA reserves the right to stop funding the project if protection is not adequate for ultimate commercialization efforts.

Protection of IP vs publication

TRxA recognizes the need for publishing in the academic environment for promotion and tenure considerations. With that said, it is requested that adequate efforts are made to delay publication if the project team deems this in the best interest of the project's future licensing opportunities and thus the ability to bring the new medical product towards patient care. Options should be explored to avoid using graduate students or other trainees on the project, who are especially vulnerable to the need to publish to finalize their training. Instead, it is recommended that professional technicians be utilized to execute the work, should publication restrictions be anticipated. With respect to the PI's performance metrics, it should be explored to what extent patent applications can be counted towards promotion and tenure decisions, to further support the delay of publication while not negatively impacting the PI's career development.

Timing of publication

Patent applications become public 18 months after the priority date. Therefore, should the project team deem it in the best interest of the commercial prospects of the project to postpone publication, this can only be delayed to a maximum of 15 months after the priority date. This allows the remaining 3 months for manuscript submission, review and potential revisions, to allow simultaneous publication of the patent application with the manuscript, and not give potential competitors more lead time than necessary.

Notification of publication and recognition language

(Plans for) submission and publication of manuscripts will be tracked in the monthly project team meetings while the project is actively being supported by TRxA. Should manuscript submission and/or publication happen post active TRxA funding, TRxA will need to be notified of publications during follow up reporting, which will be at minimum on an annual basis.

In publications, to recognize TRxA support, please include the following language: "This publication was supported by Critical Path Institute's Translational Therapeutics Accelerator (TRxA)."

Commercialization

The goal of TRxA's support is to improve the likelihood of commercialization of academic drug discovery projects, whether through licensing with an established industry partner, or through venture-backed company formation. The responsibility and decision making for these commercialization efforts ultimately lie with the university's tech transfer office (TTO) and/or licensing office, with TRxA only serving in an advisory role.

Conflict Resolution

It is anticipated that most differences of opinion on scientific direction, IP protection, or timing of publication can be resolved within the project team by building consensus, keeping in mind the ultimate goal of getting new therapies to patients. Neutral, external consultants can be engaged to provide additional expert advice, to complement the project team's experience. These consultants can be engaged by any party associated with the funded project. However, should consensus be elusive to achieve, the issue can be escalated to an adjudicating committee, composed of leadership from the university and Critical Path Institute. The project team will agree on the final composition of this body and could include individuals such as the Dean of the PI's School or the Vice President of Research at the university, the head of the TTO, the Chief Science Officer of Critical Path Institute and a representative of the Frederick Gardner Cottrell Foundation, which funds TRxA; external consultants could also be included. It is recommended to have a small, odd number of individuals comprising this committee, such as a minimum of three or a maximum of five individuals.

Reporting

The project team will meet monthly via Zoom, Microsoft Teams or a similar platform, to provide a status update and ensure alignment on next steps for the coming weeks. TRxA will provide a template agenda for these meetings to streamline information sharing. Expenditure reports shall be included in monthly project team meetings.

A written report is expected at the 6-month mark; this will be reviewed by TRxA's Scientific Advisory Committee, who will provide feedback on progress and direction. This report is expected to contain both technical and financial information.

A final report will be expected within 60 days of the end of the grant period. Similar to the 6-month report, this submission is expected to contain both technical and financial information. The Scientific Advisory Committee will once again review this report and also provide a recommendation to TRxA's Programmatic Review Board (PRB) for continuation of funding beyond the initial grant period. The PRB will make the final decision on the opportunity to continue funding, depending on progress but also availability of funds in the TRxA portfolio. Exact requirements and process for continuation of funding will be shared towards the end of the project period.

Templates will be provided for all required reports.