

<b>Participating Organization(s)</b>	National Institutes of Health (NIH)
<b>Components of Participating Organizations</b>	National Center for Advancing Translational Sciences (NCATS)
<b>Research Opportunity Title</b>	Biomedical Data Translator: Performance Phase
<b>Activity Code</b>	OT2 – Other Transaction Award
<b>Announcement Type</b>	New
<b>Related Notices</b>	None
<b>Research Opportunity Announcement</b>	OTA-24-027
<b>Assistance Listing Number (ALN)</b>	93.350
<b>Funding Opportunity Purpose</b>	These awards will support the continued development of the Biomedical Data Translator, a resource designed to support biomedical researchers in generating new hypotheses through the development of highly connected knowledge graphs representing knowledge from many disparate data sources.
<b>Objective Review</b>	Objective review will be conducted within 6 weeks of the application due date by a panel of federal employee reviewers.  Applicants will not receive feedback from the reviews.
<b>Funding Instrument</b>	The funding instrument is the Other Transactions Award mechanism.  This funding opportunity will use the Other Transactions Authority (OTA) governed by 42 U.S. Code § 282 (n)(1)(b).  An assistance mechanism that is not a grant, contract, or cooperative agreement. Policies and terms for individual OT awards may vary between awards. Each successful application is therefore issued with a specific governing award agreement, which is negotiated with the recipient and may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape, performance and/or availability of funds.
<b>Eligibility</b>	See Eligible Applicants section of this announcement
<b>Funds Available and Anticipated Number of Awards</b>	NCATS intends to commit approximately \$8.5 million in FY 2025 to fund up to 4 awards.  Future year support is contingent upon the availability of funds, scientific need, and project evaluation.
<b>Award Budget</b>	Budgets are not limited but must reflect the actual needs of the proposed project.  Performance and success towards program objectives will be routinely evaluated. Decisions regarding continued support will be based on the outcome of those evaluations.
<b>Award Project Duration</b>	Up to 5 years

<p><b>Application Submission Instructions</b></p>	<p>Applicants must submit applications via the <a href="#">NIH eRA ASSIST system</a> by 5:00 PM local time on the due date (see Key Dates below). To submit an application via ASSIST, the applicant organization must be registered in <a href="#">eRA Commons</a> (See Submission Instructions), which may take several weeks or more to complete. Applicants should therefore begin the registration process as soon as possible. Once the organization is registered, the individual(s) with the roles of Signing Official (SO) and Principal Investigator (PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process. (If an individual plans to serve in both roles, they will need two separate sets of credentials.) Complete applications must be submitted via <a href="#">ASSIST</a> by the SO. Use OTA-24-027 in the Opportunity Number field. <a href="#">Here are instructions for submitting applications</a> via the NIH eRA ASSIST system. Technical assistance is available from the <a href="#">eRA Service Desk</a>.</p> <p>On the <a href="#">eRA Commons</a> home page, select the “Register Organization” link for more details.</p> <p><b>Submission and Contact Information.</b> Applications should be submitted by the proposing entity’s Signing Official (SO) via NIH eRA Commons ASSIST no later than August 28, 2024, by 5 PM local time. If applicants are not registered in eRA or experience difficulty with submission, please contact the eRA Help Desk by <a href="#">submitting a Web Ticket</a>.</p> <p>If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the <a href="#">Dealing with System Issues</a> guidance.</p>
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**Key Dates**

Post Date	July 17, 2024
Last Modified Date	July 30, 2024
Letter of Intent Due Date (optional)	<p>August 15, 2024</p> <p>A letter of intent is recommended but not required and is not binding. An email with the LOI should be sent to translator-questions@nih.gov on or before the indicated date. All Principal Investigators and other relevant institutional officials should be copied on the correspondence.</p>
Application Due Date	August 28, 2024 by 5pm local time. Applications must be submitted via NIH eRA Commons ASSIST. See Application Submission Instructions.
Anticipated Review	October 2024
Earliest Start Date	December 1, 2024

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## Background and Overview

### Issue/gap being addressed

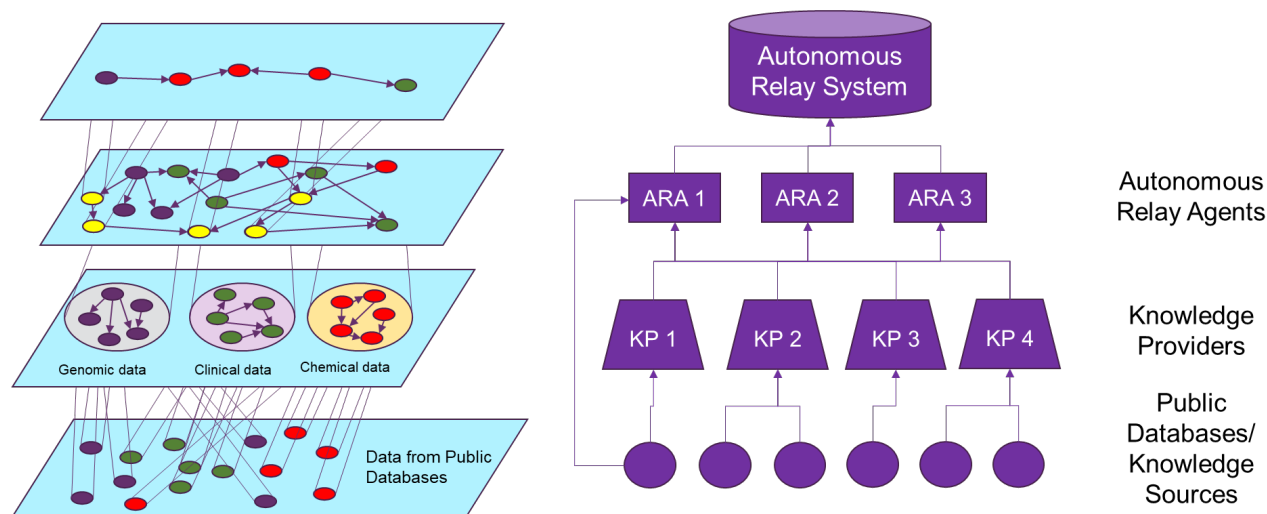
In the pursuit of biomedical research, scientists often make observations that are difficult to explain. Before investing time and resources in experimental exploration, the researcher will try to review relevant, already-known information in search of possible explanations. Currently, it falls to the researcher to manually identify potential connections or ideas by mining data and knowledge across different resources, a task that demands expertise with many different sources of data and relies upon significant recall of insights from previously published research. Further, what they find or don't find in those endeavors influences their next experimental steps and might, in fact, influence their working hypothesis. Ideally, one would mine these heterogeneous data systematically to gain insights into the relationship between molecular and cellular processes and the signs and symptoms manifested in diseases. While there have been and continue to be attempts to connect data across scientific fields, these attempts have been met with myriad difficulties, including issues with data heterogeneity, limits on the use of data, and introduction of errors by computational systems that can be difficult to track down. The NCATS Biomedical Data Translator endeavors to be a broadly used system that gathers information from different sources and uses the aggregated knowledge as building blocks to report existing information that may help explain an observation or aid in the construction of cohesive hypotheses.

### Overall goal of the Biomedical Data Translator Program

The purpose of the program is to accelerate translational research by developing a system to augment human reasoning by aggregating relevant information from hundreds of data and knowledge sources in response to biomedical research queries. With the alpha release of the Biomedical Data Translator ("Translator") [user interface](#), the system serves as a resource for computer-assisted exploration and construction of new research hypotheses by connecting and distilling existing empirical knowledge spanning all types of biomedical data, including environmental, molecular and clinical data.

Translator has been proven as a multi-modal computational tool that leverages [multiple types of existing data sources](#), including objective signs and symptoms of disease, drug effects and intervening types of biological data relevant to understanding pathophysiology. Translator connects a variety of data types using both derived knowledge and well-curated data sources, presenting a user with the most relevant data to help augment their own analysis of translational research problems. In doing so, the Translator Consortium facilitates classification of diseases based on a set of molecular and cellular abnormalities. This enables recognition of and therapeutic development for conditions with a shared molecular etiology that might manifest differently in the clinic. Translator is dynamic and transparent, able to incorporate new data and information as they become available, and able to accommodate a variety of analytical approaches to assist the generation of hypotheses. Translator is and will continue to be an [open source](#) project, completely publicly available for any user.

Translator is currently capable of revealing potential relationships across a multitude of disparate data types, from clinical signs and symptoms to cellular and molecular events to environmental exposures. Up to this point, the focus of the user interface for Translator has been on enabling researchers to find connections using a set of specific query templates that are based on feedback received from users, with expansion of query templates as a focus of the Development phase of the program. The system accesses information from many disparate graphs created and maintained by knowledge provider (KP) teams, through the efforts of several autonomous relay agents (ARAs), and each of these ARAs return potential results to match the query sent from the user interface. These potential results are then merged and collated by the Autonomous Relay System (ARS), built and maintained by NCATS intramural researchers. Results are then displayed to users through the Translator User Interface, which is being developed through a contract. All this is accomplished through the use of standards that were built specifically for the Translator program such as the [Translator Reasoner API](#), as well as standards used by a larger set of data science projects in biomedicine, such as the [Biolink Ontological Model](#). Software resources such as [Node Normalizer](#), [Name Resolver](#) and other generalized Translator software resources are key to harmonizing the disparate data in order to seamlessly integrate it across the different tools. All the current Translator software tools are open source and details about each can be found in the [SmartAPI Registry](#). The returned results are combined where possible into knowledge graphs which represent the combined evidence and provenance coming from all the software tools that contributed. The scope of Translator has been left intentionally vast to leverage biomedical data of all types to aggregate data with links to original sources across the vast subfields of biomedicine to assist users with their reasoning. This effort requires broad teams of clinical research, basic research and data science experts to work together in a highly collaborative manner with active program management.



**Figure 1: The current architecture of the Biomedical Data Translator program.** Public databases/knowledge sources are mined to create knowledge graphs which are made accessible by knowledge provider (KP) software tools. These graphs are accessed by autonomous relay agents (ARAs) which perform machine reasoning to aggregate relevant information that will augment more traditional searches conducted by researchers when generating new hypotheses. ARAs' responses to user queries include the evidence, provenance and scores associated with each result, which are passed to the Autonomous Relay System (ARS), maintained by NCATS Intramural scientists. The ARS merges similar results where possible and interacts with the Translator User Interface to display these results to users.

## Intent of the Biomedical Data Translator Performance Phase

With the completion of the Development phase of the Translator program, NCATS has built a system with incredible potential for further development which is already making significant progress in supporting hypothesis generation for translational researchers, particularly in the drug repurposing space. The queries that Translator supports so far were selected based on feedback from prospective users of the system and have been purposely limited to make sure that testing and validation infrastructure could be implemented.

The Performance phase of the program will have three major goals:

- 1) expand the query types supported by the Translator while maintaining a strong emphasis on result quality;
- 2) implement new functionality to improve the transparency of the system, including significant improvements to the presentation of evidence and provenance of results to users as well as the ability to integrate the user's own data into Translator's reasoning; and
- 3) improve system code and standards to optimize performance and support thousands of active monthly users by the end of the Performance phase.

## Objectives

During the project period, award recipients are expected to research and develop software and knowledge graphs that support the Biomedical Data Translator program by employing novel analytic approaches to integrate disparate yet high-value biomedical data and knowledge enabling Translator to address challenging translational research questions. An award recipient should expect to contribute one or more KPs and one or more ARAs (see Figure 1 above). The research and development of shared resources for Translator, as well as close collaboration with the Translator user interface development team, will be important aspects of this work.

## Data and Software Sharing

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products and procedures to improve human health. The NIH expects and supports the timely release and sharing of final research data, software and tools that support the publication of these data from NIH-supported programs for use by other researchers. The goal of this programmatic effort is to produce data, software and tools that are open source and available to any user, without a requirement to subscribe to proprietary resources or tools to be used. NCATS expects that this project will be intensely collaborative among research partners and NIH staff, and that the unrestricted exchange of source code and software tools written as part of this program will be essential to a successful outcome. All software source code must be open source and deposited into a [program-directed source code](#)

[repository maintained through GitHub](#). Data should be shared publicly unless concerns about personally identifiable information (PII) are justified by the award recipients and agreed upon by program staff.

## Meetings and Collaboration

All recipients will be expected to collaborate with both NCATS staff and other recipients and expected to participate in multiple weekly and monthly conference calls in addition to periodic face-to-face meetings. In-person meetings help to foster innovation and collaboration. At these meetings, participants will examine and improve upon the foundational work completed by Translator teams during earlier phases of the program, as well as implement new functionality and data integration to address the needs of the translational research community. NCATS anticipates holding three consortium-wide working meetings per year, at least two of which will be in-person, with virtual meetings and additional smaller working meetings planned as necessary to facilitate collaborations between teams. Applicants should budget for travel for their teams to attend two in-person meetings in the contiguous U.S. per year. Note that applicants' past experience with large-scale collaborative software development and incorporating community-contributed source code will be important considerations for funding.

## Unfunded Collaborations

The Biomedical Data Translator Consortium is a diverse and inclusive group of researchers who work together to build a complex software system. In some cases, this necessitates collaboration with those outside the consortium proper. NCATS expects award recipients to adhere to the following guidance during the Performance phase.

## Definitions

**Unfunded collaborator:** an investigator who is not employed by or otherwise affiliated with a direct Translator award recipient or a subaward of such an award, who wishes to contribute to the development of the overall Translator system or a software component thereof.

**Home team:** a Translator award recipient team willing to take responsibility for the involvement of a particular unfunded collaborator in the Translator consortium and for their conduct.

**Institutional collaborator:** employees of a direct Translator award recipient and/or subaward partner who do not have paid effort on the OT award are not considered unfunded collaborators. Collaboration within a researcher's home institution is encouraged. If a collaboration within a researcher's home institution becomes frequent enough to warrant paid effort, the award recipient should consider including some paid effort for the collaborator in their budget request.

**Subject matter experts (SMEs):** A biomedical researcher or other scientific expert who provides feedback on specific use cases for Translator, helping to improve Translator results within their area of



expertise. SME involvement is generally limited to providing expert feedback on the output from Translator within a research field or disease space.

## Interactions with Unfunded Collaborators

To facilitate the collaborative nature of the program, the following guidelines should be followed by award recipients when interacting with unfunded collaborators:

1. When the involvement of someone outside of the consortium goes beyond the occasional consultation of a SME regarding a specific disease or case study, they should be onboarded to the consortium as an unfunded collaborator.
  - a. Each unfunded collaborator must be associated with a “home team” which; one of the funded Translator teams who is willing to take responsibility for their involvement in the program and their conduct as collaborators, and who will ensure that the unfunded collaborator understands the expectations for their interactions.
  - b. The home team will request via email to NCATS program staff that the unfunded collaborator be included in the NCATS Google Drive as well as the Translator Slack instance, and detail which committees/working groups, if any, they should be included in for the purposes of Zoom/calendar invitations. [Unfunded collaborators should format their usernames in the Translator Slack as “<Your name> <Home Team> (UF)”.]
  - c. Unfunded collaborators may not act as a representative of the funded home team for the purposes of voting on decisions made during committee/working group meetings.
  - d. While suggestions of unfunded collaborators are welcome, and they are free to share their ideas and their own scientific efforts, unfunded collaborators must clearly identify themselves as an unfunded collaborator when making suggestions about the direction of work performed by other members of the consortium.
2. Unfunded collaborators are asked to recognize the consortium in publications or presentations that result from work using the Translator system, as described in the Communications section above. In addition, publications from unfunded collaborators that involve the use of Translator must follow the guidelines established by the Translator Publications Committee.
3. The term “unfunded collaborator” does not preclude a funded Translator team from making a financial arrangement for paid consultation work with such a collaborator. If an unfunded collaborator is asked by a different Translator award recipient to perform paid consultation work, the unfunded collaborator’s home team should be made aware of this arrangement in writing by the paying Translator award recipient beforehand. Like any new expenditures, new paid consultations of this type require prior approval from NCATS.

Though the need is not anticipated, if interactions with an unfunded collaborator ever become strained or distract from Translator project progress, any Translator team member may make a request to NCATS

program staff that the collaboration be discontinued. Program staff will review the request and may ask that the unfunded collaboration be terminated, and the collaborator be offboarded from the program.

## Guidelines for Translator Collaborations

Translator is a diverse and highly collaborative program built on open-source software and open access data. This focus on open science necessitates collaborations with outside investigators who have an interest in seeing Translator succeed, and whose own research may benefit directly from the systems and knowledge graphs that the consortium is building. These “unfunded collaborators” are an important part of the Translator ecosystem, but the nature of this work also necessitates some processes that ensure that the consortium’s work is properly acknowledged and cited in press releases and publications resulting from these collaborators, as well as to mitigate any misuse of Translator resources or prioritization of increases in cloud computing cost decisions.

## Communications

When working with collaborators of any kind, including SMEs, award recipients will need to ensure that communications with them make it clear that the project is part of the Biomedical Data Translator Consortium, and that any publications or presentations that result from work that used the Translator system should include the following language: “Research reported in this [publication, release] utilized the Biomedical Data Translator system, funded by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, as a resource. No direct funding support from NCATS was provided for this project. The content is solely the responsibility of the authors/presenters and does not necessarily represent the official views of NIH or NCATS.”

## Eligibility

Applications will be accepted from organizations as defined in the categories below:

### Organizations

NOTE: Organizations are not limited to a single application under this ROA. Organizations choosing to submit more than one application must ensure there is no duplication of effort, budget, activity, or research in the application submitted.

#### Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:
  - Hispanic-serving Institutions
  - Historically Black Colleges and Universities (HBCUs)

- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

#### Nonprofits Other Than Institutions of Higher Education

Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

#### For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

#### Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession
- Eligible Agencies of the Federal Government-NIH Intramural Program

#### Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

All applicants will be subject to financial analysis and risk assessment conducted by NIH staff.

#### Multiple Principal Investigators

More than one individual may be named as Principal Investigator on a single application, and given the highly collaborative nature of the program, this is encouraged. The applicant organization must designate one of the PIs as the Contact PI to serve as a primary point of contact. The Contact PI must be listed first on the application and must be associated with the applicant organization. The Contact PI is responsible for communication between the PIs and NIH but has no special authorities or responsibilities within the leadership team. Responsibilities of the Contact PI may include communication between the leadership team and NIH, assembly of the application materials, and

coordination of progress reports. The contact PI must be employed by or affiliated with the applicant organization. Any given investigator may only be named as contact Principal Investigator on a single application.

If a multiple Principal Investigator (MPI) application is submitted, a separate Leadership Plan is required. The Leadership Plan is limited to one page and should be uploaded as a separate attachment in the personnel section. The Leadership Plan should include a rationale for choosing a multiple PI approach. The governance and organizational structure of the leadership team should be provided that describes communication plans, processes for decision-making, and procedures for resolving conflicts. The roles and administrative, technical and other responsibilities should be delineated for each MPI.

## Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components **are** allowed. Foreign components are defined as the performance of any significant element or segment of the project outside of the United States either by the recipient or an individual employed by a foreign institution, whether or not award funds are expended. Prior approval is required for all foreign components.

## Systems Registration

Applications will be accepted only from the types of organizations listed in the Eligibility section of this announcement.

Applicants must submit the full application via the [NIH eRA Commons ASSIST](#) system by 5:00 PM local Time on the due date (see Key Dates). Use OTA-24-027 in the Funding Opportunity Announcement field.

Applications must be prepared and submitted using NIH's ASSIST. Complete applications must be submitted by the recipient Signing Official (SO). The organization must be registered in eRA Commons with one person designated as the Principal Investigator (PI) and one person designated as the SO. If an individual plans to serve in both roles, they will need two separate sets of credentials. The SO signature certifies that the applicant can provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded for the performance of the OT award-supported project or activities resulting from the application.

Applicants should begin the registration process early as the entire process can take several weeks to complete. It is preferred, but not required, that all key personnel also be registered in eRA Commons prior to submitting an application. Applications should be submitted on or before the "application due date" shown under the "Key Dates" section of this announcement in text-recognizable PDF (Adobe) format, use 11-point font with 1" margins and be single-spaced. The sections of the application should be combined and uploaded as one attachment, titled Translator\_PILastName\_OrgName.pdf. In addition

to the single pdf submission, applicants will be required to enter the abstract, specific aims and leadership (where applicable) sections into specified fields within ASSIST.

All applications should include the following sections, with maximum page limits listed:

<b>Section</b>	<b>Page limit</b>
<b>Title page</b>	1 page
<b>Abstract</b>	1 page
<b>Specific Aims Vision Statement</b>	1 page
<b>Project Plan Narrative</b>	5 pages
<b>Project Milestones</b>	10 pages
<b>User Engagement Plan</b>	2 pages
<b>Personnel</b>	5 pages per person
<b>Resources</b>	1 page
<b>Data Sharing and Collaboration Plans</b>	1 page total
<b>Budget</b>	No limit

Note: Applications with multiple PIs must also include a leadership plan, limited to one page. If applicable, include letters of support.

## Award Governance

The NIH will actively engage with award recipients to establish the overall vision and capabilities for Translator as well as oversee the effort of the recipients to achieve the vision.

### NIH Roles and Responsibilities:

**Other Transactions Agreements Officer (OTAO):** NIH employee responsible for legally committing the government to an OT award. The OTAO is responsible for negotiating and monitoring the financial and administrative requirements of the award, as well as terms and conditions. The OTAO is the focal point for receiving and acting on requests for NIH prior approval and is the only NIH official authorized to change the funding, duration, or other terms and conditions of award.

**Other Transactions Agreements Specialist (OTAS):** NIH employee with delegated responsibility for administrative and financial aspects of the award and is generally the first line of official OT correspondence with the applicant and/or recipient.

**Other Transactions Program Official (OTPO):** NIH employee who provides day-to-day programmatic oversight of individual awards, working closely with the OTAO. The OTPO ensures the successful implementation of Translator by considering input from other federal experts, award recipients, and collaborators. The OTPO evaluates and reviews strategic planning activities and award performance, recommends approval and acceptance of deliverables to the OTAO, and, if warranted by progress or

evolving program priorities, recommends budget adjustments to the OTA0. Additionally, the OTPO may propose creation, adjustment, or removal of milestones and deliverables.

## Developing Applications

### Letter of Intent (Optional)

A letter of intent (LOI) is recommended but not required. An email with the LOI attached should be sent to [translator-questions@nih.gov](mailto:translator-questions@nih.gov) by the contact Principal Investigator or an authorized representative of their organization on or before **August 15, 2024**. Please begin the subject line of the email with the text “[LOI]”. All Principal Investigators and other relevant institutional officials should be copied in the correspondence. The LOI should include a general description of the proposed work in no more than 500 words, along with a list of key personnel and their affiliations (please do not include full CVs or biosketches).

## Application Content

### Title Page (limited to one page)

The title page should include all the following information:

- A. Application title
- B. The Applicant Organization:
  - a. Legal name and if applicable, the legal name of all partners
  - b. Entity address and contact information
- C. Name and contact information (including email and phone number) for the Principal Investigator who will serve as the application contact (with NIH Commons Account information), any Multiple Principal Investigators, and other key persons
- D. The name and contact information (including email and phone number) for the Applicant’s Signing Official, the person authorized to negotiate and bind the Applicant as a signatory to the Other Transactions award
- E. Total cost requested

## Abstract (limited to one page)

Provide a short summary of the application.

## Specific Aims Vision Statement (limited to one page)

The specific aims vision statement should be limited to one page and describe:

1. The problem that the applicant is trying to address. This should be specific to the application, not the problem Translator is trying to address.
2. Describe unique aspects of the proposed software tools, what dependencies on other software are anticipated, and how the proposed software tools fit into the overall architecture of Translator.
3. A plan for implementation of the project, along with examples of what types of questions the proposed tools or data sources will allow Translator users to address and how the proposed work will improve the speed, efficiency, and accuracy of results.
4. Describe how the approach is different from other available tools, and the strengths and weaknesses or vulnerabilities of the approach.

## Project Plan Narrative (limited to 5 pages)

The project plan narrative should clearly describe 1) how the milestones described will ensure the project goals will be achieved 2) how the expertise and resources that the applicant can provide will be used to collaborate with NIH staff and other awardees to address project goals and integrate new data sources into the overall Translator architecture; and 3) potential challenges, gaps and barriers to implementing the goals of the proposed project, which may include barriers to integrating data sources, scoring and ranking returned results, and/or developing tools to make the best possible use of data sources and considering the limitations of the current Translator standards (based on the documentations provided [here](#)). Note that, as described in the Objectives section above, the project plan must include proposed work on, at minimum, one or more KPs and one or more ARAs. It will also be important to confirm your proposed tools' compatibility with extant standards that Translator uses, such as the [Biolink Model](#), the [Translator Reasoner API](#), and the [SmartAPI Registry](#), or to describe your plans to bring your tools into alignment with these standards.

Graphs, pictures or data tables must be included in the body of the text (not as separate attachments) and will count against the 5-page limit.

## Project Milestones (limited to 10 pages)

Provide a description of annual milestones for the full (up to five-year) proposed project period and associated costs (total cost per milestone) in up to 10 pages. This document should include a detailed description of the planned process of moving from standards to implementation.

Note 1: Applicants must ensure that the total budget request is consistent with the sum of specific item budget estimates in the Milestones and Deliverables table for the project.

Note 2: requested costs for the task should include all the costs for personnel, equipment, facilities, other resources, travel, and other associated costs.

Note 3: The continuous integration, test, and production environments (referred to as “CI”, “TEST” and “PROD”, respectively) are provided by NCATS at no cost. A development environment (referred to as “DEV”) should be provided by the applicants’ organizations and may include cloud or on-premises computing resources as needed. Please include the costs for supporting DEV environments in your budget.

Note 4: Total cost (direct and indirect) for the tasks should be provided.

Note 5: Where appropriate, project vulnerabilities and associated mitigation plans should be included.

### Example Project Milestones and Deliverables

Year 1 Milestone 1 descriptive goal		
Y1 M1.1 Bulleted list of tasks	Bulleted list of deliverables	\$30,000 Estimated total costs
Y1 M1.2 Bulleted list of tasks	Bulleted list of deliverables	\$10,500 Estimated total costs
Year 1 Milestone 2 descriptive goal		
Y1 M2.1 Bulleted list of tasks	Bulleted list of deliverables	\$45,5000 Estimated total costs
Y1 M2.2 Bulleted list of tasks	Bulleted list of deliverables	\$5,000 Estimated total costs
Year 2 Milestone 1 descriptive goal		
Y2 M1.1 Bulleted list of tasks	Bulleted list of deliverables	\$20,000 Estimated total costs
Y2 M1.2 Bulleted list of tasks	Bulleted list of deliverables	\$3,000 Estimated total costs

## User Engagement Plan (limited to 2 pages)

Describe how you will identify a diverse set of researchers who can provide input that may help guide development of functionalities of Translator, how you will engage those researchers and the cadence of those engagements. Importantly, engagement of users outside of the principal investigators (PIs) primary organization(s) is required. Please include details on how you intend to facilitate the sharing of user research outcomes with the consortium, how you plan to adapt your software based on user feedback, and how you plan to maintain user engagement for the duration of the project. While researchers participating in User Engagement Research may have a specific use case or interest, the



feedback provided should be analyzed and prioritized in the context of the overall impact for all components of program. Sharing feedback between teams is intended to guide the prioritization of development opportunities, such that expanded features are valuable to both the user engagement participant and the general user.

## Personnel

Include a CV or NIH biosketch (not to exceed 5-pages per person) for each of the key personnel who have committed to participating in the project if it is awarded. Do not include unfunded collaborators as part of the Personnel section. In the context of this program, it is especially important to highlight past contributions of personnel to existing open source projects, standards, and initiatives as well as evidence of the ability to work collaboratively.

Include a list of other support as part of each biosketch or CV submitted. For projects that do not have future year commitments (such as Other Transactions Authority awards), please indicate the project duration that was proposed.

Provide a table listing all personnel, including all to be named personnel, role on the project, and percent effort to be committed. Ensure that key personnel are clearly indicated in the table. While there is no minimum effort level required for the PI or MPIs, due to the intensive nature of this program, two team members with a minimum of 50% effort each is required. Identify which individual will be the primary person responsible for user engagement activities. Do not include salaries here.

## Resources (limited to one page)

Include a 1-page description of resources available for the project. Note that software tools are expected to be developed as open source and will be deployed to NCATS-supported cloud computing systems. NCATS will provide three cloud environments (CI, TEST, and PRODUCTION), providing access to these systems as required to support the software developers. It is recommended that for pre-deployment software development purposes, each team have access to a DEVELOPMENT environment, either cloud or on-premises at their home organization.

## Data Sharing and Collaboration Plans (limited to one page total)

Applicants must include a data sharing plan and a collaboration plan, up to 1 page total, which must address the requirement for open source code deposition for the project. Note that all source code will be required to be deposited into an [NCATS-managed GitHub repository](#), and all software tools must be registered in the [SmartAPI Registry](#). If data sharing is not possible, state why. If data sharing is limited, the applicant should explain such limitations in the data sharing plan, including their potential impact on the proposed open source project. NIH's data sharing policy may be found at the following website: <https://sharing.nih.gov/>. Note that past experience with collaborative design of software that includes

community-contributed code will be an important consideration of funding and must be described as part of the collaboration plan.

### Budget (no page limit)

In the ASSIST Core tab, applicants should enter the total dollar number in the field of Total Requested Funds.

The proposed budget must provide a realistic and well-justified cost proposal for performing the work over the period requested (up to 5 years). The budget must reflect the needs of the proposed activities. The primary applicant is responsible for including all partners/third parties' (i.e., subrecipients/subcontractors) budgets and budget justifications. The detailed budget request should be provided for each year of the proposed work period. Travel budgets should include costs for in-person attendance of personnel at two annual Translator working meetings in the contiguous United States. For each year, it should provide the overall expected cost for each of the following categories: personnel, equipment, travel, funds for partners/third parties, if applicable, other direct costs, and total cost (with indirect costs included). A budget justification must be provided for all budget items. Organizations with an established Facilities and Administrative (F&A) rate may include the F&A costs. Organizations without an established F&A rate may propose a rate for review and negotiation.

Budgets must adhere to the latest NIH salary limitation notice [https://grants.nih.gov/grants/policy/salcap\\_summary.htm](https://grants.nih.gov/grants/policy/salcap_summary.htm).

Partners/third parties are required to provide details of cost breakdown. Prime applicants should follow their internal policies and procedures to calculate partner/third party budgets.

It is anticipated that in addition to initial milestone negotiations, after the kick-off meeting, some originally proposed milestones might be altered or removed, and some new milestones may be added. The estimated budget should be based on the milestones proposed in the application. During negotiations, program staff may request that a successful applicant add collaborators to their planned project to address any gaps in expertise identified. Should this occur, appropriate funding will be negotiated.

### Letters of Support and References (no page limit)

Letters of support for all collaborators/other significant contributors, consultants and sub-award sites should be provided. Letters should describe the type of contribution or consultation that will be provided (architecture, software development, user perspective, etc.) and must include the stipulation that all software generated by partners/third parties will be open source and shared through GitHub as described in the Data Sharing and Collaboration Plans section (above). Letters that are written for the sole purpose of endorsement should not be included and will not be considered during review. However, a list of previous collaborators (limited to one page) who may be contacted as references as to

the applicants' history of collaborative work on large-scale projects should also be included, as applicable.

## Human Subjects

**NOTE: No NIH defined clinical trial activity will be funded through this ROA.** (Please refer to the NIH [Clinical Research](#) website for details.)

For research involving human participants, NIH has specific requirements for research staff and policies regarding research conduct, safety monitoring, and reporting of information about research progress. If funded, all human subjects research must be approved by an Institutional Review Board (IRB) and be conducted under a Federal Wide Assurance (FWA). Before engaging in any human subjects research, recipients must obtain a Federal Wide Assurance (FWA) from the DHHS Office for Human Research Protections (OHRP) (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html>), and comply with 45 CFR 46 (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>), and, as applicable, any relevant FDA regulations (e.g., 21 CFR 11, 50, 54, 56, 312, and 812) (<https://www.fda.gov/medical-devices/medical-device-databases/code-federal-regulations-title-21-food-and-drugs>) governing the protection of human subjects and the conduct, management, and oversight of clinical trials. Recipients will need to provide to the NIH Agreement Officer/Specialist, the NIH staff person who is authorized to award Other Transactions, evidence of an active FWA prior to the commencement of any human subject research activities contemplated under this award. Further, recipients must comply with all applicable laws and regulations relating to the privacy and confidentiality of human subjects. In addition, for research involving human participants, recipients will be required to provide the number of participants they plan to recruit; NIH will monitor progress made towards recruiting that number.

## Objective Review Process

Applications to this ROA will be reviewed using a process referred to as Objective Review.

### Non-Responsive Applications

Applications will be considered non-responsive if any of the following are true:

- The list of personnel for the project does not include at least two team members with a minimum of 50% effort each.
- The project plan narrative does not include work on one or more KPs and one or more ARAs (see Objectives section above for additional information).
- The user engagement plan does not include proposed engagement of potential users of Translator outside of the primary organization(s) of the principal investigators (PIs).

- Any clinical trial activity is proposed as part of the project plan or milestones.
- Any funding to support wet lab or clinical studies is requested.

Non-responsive applications will not be reviewed.

## Review Process

Responsive applications will be reviewed by subject matter experts via an objective review process. An application evaluation group, convened by NCATS, will include NIH and other federal government staff reviewers. Reviewers will be asked to review and comment on the personnel, resources, data sharing plan, collaboration plan and budget in the application as well as the specific considerations below. The review process will use the considerations described below to guide the subject matter reviewers on the assessment of the applications, the preparation of the written summaries and discussions between those experts and NIH program staff.

Written feedback on the outcome of the objective reviews will not be provided. NIH will not accept an appeal of the objective review or funding decision outcomes.

## Objective Review Considerations

- Previous experience with developing a software system for large-scale collaborative projects, including the incorporation of community-contributed source code:
  - To what extent is the applicant's past experience as part of consortia that were collectively building research resources appropriate to contribute to Translator's success?
  - What were their contributions in those consortia?
  - What is their experience engaging intended user communities?
- How will the proposed software tools continue to broaden the scope of possible questions that may be asked of Translator:
  - What is the problem the applicant is trying to address and how will they address the problem?
  - What kind of impact would their solution have for Translator users?
- Viability of the applicant's plan to implement their proposed projects, including specific and realistic milestones for the entire project period with consideration given to the applicant's plans to ensure compatibility of their software with established Translator data and software standards:
  - Based on the documentation provided [here](#), what barriers may be encountered given the limitations of the current Translator standards and what they propose to develop?

- To what extent do the applicants demonstrate a strong understanding of the existing standards and architecture that have been used in previous phases of the program and their ability to comply with them?
  - Are any of the tasks or deliverables not feasible or inappropriate considering the time and budget proposed? If there are, how might these proposed tasks be pared down to become more manageable (or, should the budget be increased to include the full scope of tasks)?
  - Regardless of risk or innovation, what is the most critical milestone or deliverable needed for this proposal to succeed?
  - Do any proposed deliverables present a major risk? What are the greatest vulnerabilities of these deliverables? What mitigation plan is proposed to mitigate these vulnerabilities?
  - Are there any milestones or deliverables that appear to be low risk, yet have the potential for high impact?
- Scientific complementarity of the application with other applications under consideration and other data science projects at NCATS and other federal agencies:
    - In what ways is this proposal complementary and/or unique when compared to other proposals submitted?
    - What, if any, are dependencies that are outside of the applicant's control and may create vulnerabilities in what they propose to build? How have they proposed to mitigate these vulnerabilities?
- Viability of the User Engagement Plan to ensure the usefulness of the contributions to the Translator program and to potential end-users:
    - How effective will the user engagement plan be?
    - How will the team maintain user engagement for the duration of the project?
    - Do the teams demonstrate plans to incorporate user engagement outcomes into their design strategies?
    - To what extent does the user engagement plan include a diverse user base, including users outside the primary organization(s) of the principal investigators (PIs)?
    - To what extent does the team's description of their planned analysis and implementation of user feedback represent a robust assessment and action plan?

## Assessment of Overall Impact

Reviewers will provide an assessment of the potential impact of the overall proposed activities on improving the functionality and broadening the query space of the Biomedical Data Translator.

Additionally, reviewers will be asked to identify key aspects of applications that merit additional interest. Review outcomes are likely to include recommendations that could facilitate dialogue or site visits between applicants and federal staff, leading to modifications of the milestones submitted to NIH. Components of the applications may be accepted into the final plan in whole or in part or may be omitted. The modified tasks and milestones, as shaped by the objective review process, will serve as a framework for the final negotiated terms for the resulting awards.

## Negotiations

Based on the objective review outcome, NIH will select a subset of applications and/or subsections of applications to negotiate award terms. Final funding decisions will be based on the outcome of the objective review and negotiations between the selected recipients and NIH. Agreements for all awards will be negotiated via video conference, site visit, and/or teleconferences.

NIH reserves the right to:

- Accept applications in their entirety or to select only portions of applications for award.
- Fund projects by combining applications as part of a reorganized, consolidated consortium operating under an article of collaboration, teaming arrangement, or other means acceptable to NIH.
- Remove applicants from award consideration should the parties fail to reach a finalized, fully executed award agreement, or the applicant fails to provide requested additional information in a timely manner.

## Financial and Risk Assessment

As is standard for OT programs, all applicants will be subject to financial analysis and risk assessment conducted by NIH staff.

## Special Award Terms

The complete terms and conditions of each Other Transactions award issued under this ROA are subject to negotiation and will be included in the OT award agreement between NIH and the recipient. The Special Award Terms section is provided for informational purposes only to provide prospective applicants with an understanding of key expectations and terms that may differ from traditional NIH award mechanisms (e.g., cooperative agreements/grants or procurement contracts). All terms and conditions of the award will flow down to any partners/third parties (e.g., subrecipients, subcontractors, funded collaborators) participating in the OT award. See the Unfunded Collaborators section of Background and Overview, above, for guidance on interactions with unfunded collaborators.

The use of OTA supports NIH taking a flexible approach to negotiate award terms and conditions. The OTA award mechanism allows significant ongoing involvement from NIH Program Staff and allows NIH to alter the course of projects in real time to meet overarching Translator Program goals. This means an awarded activity could be expanded, modified, or discontinued based on Program needs, achievement of agreed-upon activities, or availability of funds. During the funding period, performance will be reviewed on an ongoing basis with course corrections taking place where necessary. As a result, NIH reserves the right to fund projects in increments and/or continue or discontinue work at the end of each phase.

### Potential Addition of Partners

With mutual consent of the applicant and NIH, successful applicants might be asked to enter partnerships with entities identified and approved by NIH.

### Post-Review Submission of Milestones and Timeline

NIH will review and approve the proposed milestones for inclusion in the OT award. Those selected for funding will:

- produce and submit a written final plan with self-identified milestones and a timeline to be agreed upon with NIH staff (may be informed by negotiations); and
- achieve milestones as defined in a binding, written award agreement to be developed and agreed upon by NIH and the recipient.

### Payment

The OT award will use the Payment Management System (PMS) operated by the DHHS Program Support Center. Payments by PMS may be made by one of several payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis as specified in the terms of the award. Generally, payments may be aligned with achievement of milestones, or a payment schedule could be negotiated prior to issuance of the award to minimize the amount of time that elapses between the transfer of funds from the Federal Government and disbursement by the recipient. NIH and/or applicants may negotiate non-milestone-based payment structures such as cost reimbursement for part or all of the award period.

### Reporting

The terms and conditions of the award will address this requirement as appropriate based upon the final negotiated and agreed upon budget.

## Financial and Progress Reports:

- Recipients will be expected to provide regular progress reports to the OTPO and OTA0. The frequency and types of technical and financial reports required will be specified in the award, and will include, at a minimum, financial status reports that will establish the burn rate for the project and an annual progress report.
- A final Federal Financial report is required at the end of the award period.
- A final progress report that summarizes the project and tasks completed is required at the end of the award period.

The reports shall be prepared and submitted in accordance with the terms and conditions requirements. Failure to submit a required report may result in discontinuance of funding support.

## Questions and Answers

Responses to questions about this ROA will be posted here: <https://ncats.nih.gov/research/research-activities/translator/performance-phase-qa>.

## Agency Contacts

Financial and administrative questions should be addressed to OTA0, Jennifer Cho, by emailing [translator-questions@nih.gov](mailto:translator-questions@nih.gov).

Technical questions regarding this ROA should be addressed to OTPO, Dr. Tyler Beck, by emailing [translator-questions@nih.gov](mailto:translator-questions@nih.gov).

## For More Information

**Questions about this opportunity** should be emailed to [translator-questions@nih.gov](mailto:translator-questions@nih.gov).

## Submission and Contact Information

Optional letters of Intent should be submitted to [translator-questions@nih.gov](mailto:translator-questions@nih.gov) no later than **August 15, 2024**.

For best consideration, applications should be submitted in ASSIST no later than **August 28, 2024**, by 5 PM local time.



## eRA Registration

NCATS uses the eRA Commons system (“Commons”) to administer OT awards. Therefore, prior to submitting your application via eRA ASSIST, it is essential that your organization, Principal Investigator (PI), and Signing Official are registered at eRA Commons. It is desirable, though not required, that other key personnel are also registered at eRA Commons. Please plan to complete the registration process early to avoid application submission problems. To register, please follow the instructions via this website: <https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era> .

1. Complete the online Institution Registration Form and click Submit.
2. The NIH database will send you an email with the link to confirm your email address.
3. Once your email address is verified, NIH will review your request and let you know of the result via email.
4. If your request is denied, you will get an email notifying you of the reason.
5. If your request is approved, you will get an email with your Commons User ID and temporary password.
6. Log into Commons with the temporary password and the system will prompt you to change the temporary password to a permanent one. Your Signing Official will be prompted to electronically sign your registration request. Please review your registration information carefully.
7. Once your Signing Official has electronically signed the request, your organization will be active in Commons, and you may create and maintain additional accounts for your organization staff.

Once you have established an eRA Commons account, the next step in the process is to formally submit your application in ASSIST, which is a component of the eRA system.

Please note that in order to receive an award, you may need to register for one or more of the following if you haven't done so already:

- [System for Award Management \(SAM\)](#)
- [Unique Entity ID \(UEI\)](#) created in SAM.gov
- [Employer Identification Number \(EIN\)](#)