Leidos Biomedical Research, Inc.

SOLICITATION/RFP NUMBER: S22-049	**DATE ISSUED:** 3/25/2022
ISSUED BY: Leidos Biomedical Research, Inc. Research Contracts Department P.O. Box B 1050 Boyles Street Frederick, MD 21702	**ADDRESS OFFERS TO/FOR INFORMATION REGARDING THIS SOLICITATION CONTACT:** **NATALIE FIELMAN** NATALIE.FIELMAN@NIH.GOV
IMPORTANT: To be considered for award, offers must be received at the location specified above by 30 DAYS FROM ISSUE. Offers must be clearly identified with the Solicitation/RFP Number listed above. **The cover letter shall acknowledge that your transmission of an offer in response to this Solicitation is valid for a period of 120 days from date of submission.**	

A. Introduction

This Solicitation is issued by Leidos Biomedical Research, Inc. (Leidos Biomed), a wholly owned subsidiary of Leidos Corporation under its Prime Contract with the National Cancer Institute (NCI/Government) at Frederick. The provisions and clauses contained herein and attached are influenced by and reflect the relationship of the parties in said Prime Contract, which was awarded and is administered under the provision of the Federal Acquisition Regulation (FAR).

B. Anti-Kickback Act of 1986

The Anti-Kickback Act of 1986 as referenced in FAR 52.203-7 is hereby incorporated into this Solicitation and any subsequent award(s) as a condition of acceptance. If you have reasonable grounds to believe that a violation, as described in paragraph (b) of FAR 52.203-7, may have occurred, you should report this suspected violation to the Leidos Ethics Hotline at (855) 753-4367 or via the internet at www.leidos.ethicspoint.com.

C. Solicitation Package

This Solicitation Package consists of three documents: (i) this one, which is referred to as the Request for Proposal (RFP) Document; (ii) draft Subcontract Document; and (iii) Subcontractor's Representations and Certifications.

D. Contract Type

The resulting Subcontract is an Indefinite Delivery Indefinite Quantity contract type. An Indefinite-Delivery-Indefinite-Quantity contract type provides for an indefinite quantity, within stated limits, of

supplies or services during a fixed period. The resulting Subcontract, and any Task Order(s) issued thereunder, are subject to the terms, conditions and provisions included therein. Leidos Biomed shall not be responsible for any charges other than those charges authorized on a Task Order basis. Leidos Biomed shall not be responsible for any other charges beyond those so ordered. The "work" will be set forth in individual Task Order Statements of Work and will be performed on either a Firm Fixed Price, Time and Materials, or Cost Reimbursable basis, **with initial tasking expected to be Firm Fixed Price**. A Firm Fixed Price contract type provides for a price that is not subject to any adjustment as a result of the Subcontractor's actual cost experience. The Subcontractor may not exceed the established Total Award Amount or Firm Fixed Price without the prior approval of the Leidos Biomed Subcontracts Administrator.

E. Instructions to Offerors

E.1. General Information

IMPORTANT – ELECTRONIC SUBMISSION:

OFFERS MUST BE SUBMITTED ELECTRONICALLY IN EITHER SEARCHABLE ADOBE ACROBAT, MICROSOFT WORD, OR MICROSOFT EXCEL FORMATS AS APPLICABLE. SAVED FILES MUST NOT EXCEED 15 MB IN SIZE; THIS MAY REQUIRE THAT A DOCUMENT BE BROKEN INTO TWO OR MORE SEPARATE FILES.

ALL OFFERS MUST BE RECEIVED BY NOON E.S.T. ON MAY 9, 2022. OFFERS SHALL BE SUBMITTED TO NATALIE FIELMAN AT NATALIE.FIELMAN@NIH.GOV.

All offer submissions must be clearly identified to include the Offeror's name, Principal Investigator's name (or Project Manager's name), and Solicitation/RFP Number.

Late offers will not be considered for award.

E.2. Questions Regarding this Solicitation—Reserved

E.3. Offerors' Teleconference

IMPORTANT:

A PRE-OFFER SUBMISSION TELECONFERENCE WILL BE HELD ON APRIL 6, 2022 AT 3 P.M.-5 P.M. This teleconference will provide Offerors the opportunity to ask additional questions and receive answers in a "live" venue.

Offerors wishing to participate in this webex conference shall register by 5 p.m. ET, Tuesday, April 5, 2022, at https://events.cancer.gov/nci/improvebiddersconference/registration.

Offerors wishing to join the audio only portion should dial 1-650-479-3207 and enter meeting number (access code) 2309 946 4764 when prompted. In a competitive Solicitation, anonymity is an important aspect to maintaining the integrity of the competition. As such, Offerors are encouraged to contact the Leidos Biomed Subcontracts Administrator to advise of their participation in an Offerors' Teleconference in lieu of identifying themselves on the teleconference.

E.4. Offeror Site Visit—Reserved

F. Proposal Instructions to Offeror

To be considered responsive to this Solicitation, the Offeror must provide and/or complete the following requirements:

- Volume 1 – Request for Proposal Document
- Volume 2 – Technical Proposal
- Volume 3 – Price (Cost) Proposal
- **Subcontractor's Representations and Certifications** (provided as a separate document with this Solicitation Package).
- An IRS Form W-9. All Offerors MUST be registered with the System for Award Management (SAM). Offerors may register with SAM at https://www.sam.gov/SAM/. The address included on the W-9 **MUST** match the address registered at SAM, and/or included with Subcontractor's Representations and Certifications. **FOR INTERNATIONAL, ALL OFFERORS MUST COMPLETE W-8BEN-E IN PLACE OF W-9. LINK MAY BE FOUND AT** http://www.irs.gov/pub/irs-pdf/fw8bene.pdf
- A draft Subcontract is provided as part of this Solicitation Package to provide Offerors with an opportunity to review Leidos Biomed Terms and Conditions. It is requested that the Offeror exercises due diligence in reviewing the Terms and Conditions prior to submitting a formal offer in response to this Solicitation and in the context of the proposed Statement of Work. Any requested exceptions or risk areas identified shall be part of the proposal submission as redlined changes to include alternate language and a justification for each proposed change in the Subcontract. Negotiations in good faith are expected; however, excessive exceptions requested may result in significant delays in award.

F.1. VOLUME 1 – RFP Document

This Volume shall contain the RFP Document with all items completed as required below and submitted as prescribed in E.1. General Information above and be clearly named Volume 1 – RFP.

Requirements:

- Complete Section J. Certifications
- Complete Section K. Offeror Representatives
- Complete Section L. Offeror Signature

F.2. VOLUME 2 – TECHNICAL PROPOSAL

This Volume shall contain the Technical Proposal Document with all items completed as required below and submitted as prescribed in E.1. General Information above and shall be clearly named Volume 2 – Technical Proposal.

IMPORTANT:

Technical Proposals shall not include cost or pricing information.

- Technical Proposals must include page numbers on all pages, including all appendices and attachments. There must also be a cover page that lists all appendices and attachments.

Requirements:

The Offeror must provide Technical Proposals that clearly demonstrate the Offeror's current capabilities to meet each of the various requirements as established in RFP Attachment 1: Statement of Work and in accordance with the guidelines set forth below. Responses shall be focused, succinct, and free of extraneous data or information responding solely to the requirements contained in the RFP Attachment 1: Statement of Work. Additionally, Technical Proposals shall be formatted in such a way to clearly cross-reference the relevant sections in the RFP Document.

Provided below is the outline of specific information to be addressed in the Technical Proposal and for maximum page limitations for each of the required sections.

F.2.a. Executive Summary (2 page limit)

The summary shall contain the most important elements from sections below but should at a minimum clearly specify the following elements:

- Brief identification and qualifications for this Solicitation of your organization/team, including any lower-tier subcontractors and their roles.
- The purpose and anticipated end result of this Technical Proposal.
- Technical and management approach discriminators.

The summary shall be on separate pages or include a section break before the rest of the Technical Proposal.

F.2.b. Technical Approach (12 page limit)

Understanding

Provide your understanding of what needs to be done, the scope of the work, the estimated length of time for the work to be finished, the challenges, and how you are going to address those challenges.

Approach

Describe a sound technical approach to the proposed work and critical technology challenges required for accomplishing proposed tasks. Describe any unique aspects of the approach, and why you believe it will be the most efficient and effective way of achieving project objectives. Describe how this approach will meet both project and overall objectives as described in RFP Attachment 1: Statement of Work.

F.2.c. Team and Key Personnel (5 page limit)

Introduction

Introduce your organization and/or team here; give an overview of the capabilities brought to address this effort.

Organization and/or Team

Describe your organization and show chain of command and lines of communication.

Describe each proposed individual's role, the percentage of their time that is being bid, and a brief description of their qualifications. Fuller experience descriptions may be included in the Appendix.

Personnel

All key personnel shall be clearly indicated. **Resume summaries for key personnel shall be included in this section, and full resumes in the Appendix**. The percentage of time each key person is proposed should be clearly indicated here.

F.2.d. Experience and Past Performance (3 page limit)

Describe the teams overall experience with development, processes, and technologies similar to those described in the RFP Attachment 1: Statement of

Work. Clearly indicate which organization on your team is providing this experience.

Provide a description of at least three projects successfully performed in the past that indicate the ability to perform on this effort. At least one of these projects should have been performed for an organization other than Leidos Biomed. Clearly indicate who on your team performed, what role was played on each of these projects, and the success criteria that were used to judge the project. Summaries shall be given here, and more complete descriptions may be included in the Appendix.

F.2.e. Project Plan and Work Breakdown Structure (4 page limit)

Describe in summary form the set of tasks that will be performed in order to accomplish project objectives.

Detail the methods for producing deliverables, allocation of staff, and other resources necessary to produce deliverables, and timelines.

Provide a draft project plan in MS Excel or PDF format as a separate attachment (no page limit). This document should contain tasks that demonstrate how objectives described in the RFP Attachment 1: Statement of Work will be accomplished. The draft project plan shall show tasks, dependences, and milestones, any milestone reviews as requested in RFP Attachment 1: Statement of Work, as well as any requested Offeror-supplied dates for deliverables.

F.2.f. Management Approach (2 page limit)

Controls

Describe your project management approach and what control mechanism you can put in place to track progress and ensure project schedules will be met in according to agreed-upon schedules.

Risk Management

Describe your overall risk mitigation strategy.

Provide an initial risk table. This table should include a list of project risks, an estimation of the severity of the risk (H,M,L), and a risk mitigation approach for that risk.

Subcontractor Management

Describe management controls to be put in place for lower-tier subcontractor management if lower-tier subcontractors are a part of the proposed team.

Financial Tracking

Describe the mechanism you will use to control budget and cost.

F.2.g. Appendix (no page limit) Technical information will not be scored

F.3. VOLUME 3 – COST (OR PRICE) PROPOSAL

This Volume shall contain the Cost (or Price) Proposal Document with all items completed as required below and submitted as prescribed in E.1. General Information above and shall be clearly named Volume 3 – Cost (or Price) Proposal.

Requirements:

Offerors shall submit Cost (or Price) Proposals that provide a budgetary estimate for the project proposed. The Cost (or Price) Proposal shall include the information required in Sections One and Two below. Budget estimates provided in response to this Solicitation will be used for planning and evaluation purposes. Any requests from Offerors to revise the original budget estimate, as the result of changes requested to the original technical approach during Subcontract negotiations, may be considered but these requests from Offerors must be accompanied by a detailed explanation of the nature and impact of the change and the need for monetary adjustment.

Section One – Cost (or Price) Proposal

The Cost (or Price) Proposal shall contain sufficient information to allow Leidos Biomed to perform an analysis of the proposed cost (or price) of the work proposed. This information shall include the amounts of the basic elements of the proposed cost (or price) including, but not limited to, labor hour rates, travel, materials, and lower-tier subcontracts.

In preparing your Cost (or Price) Proposal, the following shall be considered:

- **FAR 52.215-17 Waiver of Facilities Capital Cost of Money is incorporated in this Solicitation; therefore, Facilities Capital Cost of Money is an unallowable cost under any resulting Subcontract.**
- Offeror is to prepare their Cost (or Price) Proposal using RFP Attachment 2: Cost (or Price) Template and submit with Offer in Microsoft Excel format.
- Costs shall be broken out by task.
- Offerors shall provide substantive detail regarding the cost (or price) proposed to enable reviewers to objectively determine the reasonableness. Failure to provide a level of detail to facilitate this determination may result in the offer being considered nonresponsive.

Section Two – Cost (or Price) Justification and Documentation

In this section, provide justifications and explanations of all proposed costs. This INCLUDES explanation of the processes by which extended costs were derived and a basis for why the proposed costs should be considered reasonable. The supporting information to be provided includes, but is not limited to:

- Labor costs: Provide labor categories and a description of the position's planned role on the project. If the proposed positions have not been filled or are to be named or hired, provide description of anticipated position and estimated labor category and rate.
- Demonstration of the reasonableness of any proposed lower-tier subcontractor costs, including demonstration that the proposed rates/costs are in keeping with those normally charged for the work to be performed.

G. Proposal Evaluation Criteria

G.1. Basis for Award

Leidos Biomed intends to award a Subcontract(s) resulting from this Solicitation to the responsible organization(s) whose offer(s) conforming to this Solicitation will be of the best value to Leidos Biomed, price and other factors considered. Although technical factors are of paramount consideration in the award of a Subcontract, cost and/or price is also important to the overall award decision.

G.2. Potential Award Without Discussions

Leidos Biomed reserves the right to award a Subcontract without discussions if the Leidos Biomed Subcontracts Administrator determines that the initial offer(s) are fair and reasonable and that discussions are not necessary. Therefore, the Offeror's initial offer should contain the Offeror's best terms from a price and technical standpoint. However, Leidos Biomed reserves the right to conduct discussions if later determined by the Leidos Biomed Subcontracts Administrator to be necessary. Leidos Biomed may reject any or all offers; accept other than the lowest priced offer; and waive informalities and minor irregularities in offers received.

The assessment of the offers received in response to this Solicitation will be carefully considered against the needs of Leidos Biomed and the Government. This assessment is not intended to be a solely mechanical or mathematical analysis of an offer, but rather the product of both objective and subjective measurements and judgments of the source selection officials after consideration of the relevant information.

H. Proposal Evaluation Factors

Evaluation of the offers submitted will be considered against the following evaluation factors.

General Evaluation Criteria

H.1. Technical Approach

- The Offeror demonstrates good understanding of the scope, objectives, and challenges of this project.
- The proposed approach is capable of meeting project objectives as stated in the RFP Attachment 1: Statement of Work.
- The solution proposed is within the scope of the effort.

H.2. Team and Key Personnel

- Project Organization covers all skills needed to execute this project.

- Key Personnel have demonstrated experience in the technical evaluation factors given above that are applicable to their role.
- Evidence has been provided that Key Personnel have performed successfully in the past in the role proposed.
- Key Personnel are bid at a level of effort commensurate with their proposed role.

H.3. Experience and Past Performance

- The Offeror has demonstrated experience in the technologies and procedures required to execute this project.
- Past performance examples are for projects of similar size, scope, and technical objectives.
- Evidence of successful performance on these projects has been provided.

H.4. Project Plan and Work Breakdown Structure

- The project plan is sufficient to meet the objectives in the RFP Attachment 1: Statement of Work.
- Project schedule is reasonable given the tasks proposed.
- Goals are consistent with the scope of work guidance.

H.5. Management

- Mechanism by which budget and costs are controlled has been described.
- Project risks have been identified and risk mitigation strategies have been identified.
- Lower-tier subcontractor roles are defined (as applicable), and management controls are adequate.

H.6. Cost (or Price) Reasonableness

- Costs (or prices) proposed are commensurate with the technical tasks bid.

I. RFP Attachments

The following are considered attachments to this RFP Document:

Attachment No.	Document Description
1	Statement of Work
2	Cost (or Price) Template

The following is provided as a separate document in this Solicitation Package:

Subcontractor's Representations and Certifications

J. Certifications

J.1. Organizational Conflicts of Interest (OCI)

This certification is required to ensure OCIs do not exist for the anticipated performance of the Subcontract or that any potential OCI is identified, neutralized or mitigated when:

☐ Offeror hereby certifies that Offeror's performance of its obligations under any Subcontract that may be issued as a result of this Solicitation will not be biased because of its financial, contractual, organizational or other interests which relate to the proposed work; Offeror will be able to render impartial, technically sound, and objective assistance or advice; and Offeror will not obtain any unfair competitive advantage over other parties by virtue of its performance of the proposed Subcontract.

☐ Offeror hereby certifies that the circumstances as to why it cannot make the foregoing "No OCI Representation" certification are fully disclosed in the attached pages (Offeror to provide as a separate document in advance of full proposal) and reflect:

- The category of conflict (organizational, contractual and/or financial);
- The company, agency, organization in which you have a past, present, or currently planned interest or activity (financial, contractual, organizational, or otherwise);
- A brief description of the relationship, period of relationship and the extent of relationship (e.g., value of financial interest of work; percent of total holdings, total work, etc.).

Offerors who have potential conflicts of interest or individuals that work on CBIIT Program Level Workspace, Architecture, or Governance Teams and through this participation have access to information that might give them a competitive advantage **must certify in**

writing 2 weeks prior to the submittal due date for offer (Subcontracts Administrator should adjust the # of weeks/days appropriate to the length of the Solicitation) that these individuals have not participated in proposal preparation and must provide a mitigation plan that certifies that a firewall has been established within the Offeror's organization that provides a separation between the proposal team and the individuals who work on CBIIT Program Level Workspace Architecture or Governance Teams to insure information gained from such participation is not used in preparation of the proposal. These certifications are necessary to insure a full and open competition is conducted with no Offeror having an inappropriate competitive advantage.

If this direction is not followed, Offeror will be disqualified from the competition.

J.2. Place of Performance (FAR 52.215-6)

In performance of any Subcontract resulting from this Solicitation, the Offeror certifies that it:

☐ **Intends** or ☐ **Does not intend** to use one or more plants or facilities located at a different location from the Offeror's primary performance address as proposed in this RFP Document.

If the Offeror checks "intends", it shall provide the information for the other plants or facilities where work will be performed below:

Place of Performance	Name and Address of Owner and Operator of the Plant or Facility if Other than Offeror
Street Address, City, County, State, Zip Code	Solicitation/P.O./Subcontract Number:

J.3. Buy American Act Certification

It is the preference of Leidos Biomed that domestically procured products be utilized to the maximum extent possible in the performance of any Subcontract resulting from this Solicitation.

☐ The Offeror certifies that each end product, except those listed in paragraph (a) below, is a domestic end product and that for other than Commercial Off-The-

Shelf (COTS) items, the Offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States.

The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test. The terms "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," and "United States" are defined in FAR 52.225-1 entitled "Buy American—Supplies."

(a) Foreign End Products:

Line Item No.:	Country of Origin:

J.4. Limitations on Pass-Through Charges – Identification of Subcontract Effort—Reserved

J.5. Utilization of Small Business Concerns

In accordance with the terms of its Prime Contract, under which a resulting Subcontract will be issued, Leidos Biomed is committed to maximizing small business subcontracting opportunities to the greatest extent practicable.

In pursuit of this objective, please complete the following representation and certification providing the percentage of effort that would be conducted by **your** employee personnel during the execution of the Statement of Work as provided herein (including any optional tasks/periods, as applicable). **Note:** Any lower-tier subcontractor effort should be detailed in the Offeror's Technical Proposal.

J.5.a. Subcontracting Certification

By submission of this signed offer, Insert Organization Name hereby certifies that:

(1) % of the effort expended in the execution of the Statement of Work as provided by Leidos Biomed in Solicitation/RFP Number will be conducted by employees of this organization and;

(2) That further lower-tier subcontracting opportunities ☐ do or ☐ do not exist.

[**Not applicable if Offeror is a small business concern.**]

J.5.b. Subcontracting Plan (FAR 52.219-9)

Offers to perform a resulting Subcontract that is expected to exceed $750,000 and that has subcontracting possibilities, shall submit an acceptable subcontracting plan. If the apparent successful Offeror fails to negotiate a subcontracting plan acceptable to Leidos Biomed during pre-award, the Offeror will be ineligible for award.

The Leidos Biomed Subcontracting Plan template can be found at: https://frederick.cancer.gov/sites/default/files/2021-11/Small%20Business%20Subcontracting%20Plan_0.pdf. Offeror must also provide with the proposal the name, title, telephone number, and e-mail address of the individual who will administer the subcontracting plan.

J.6. Certificate of Minimum Labor Category Requirements—Reserved

J.7. Office of Laboratory Animal Welfare (OLAW) Certification—Reserved

J.8. Protection of Human Subjects – Federal Wide Assurance—Reserved

J.9. Restrictions on Use of Human Subjects—Reserved

K. Offeror Representatives

K.1. Offeror Authorized Representative

The following individual is the designated representative of the Offeror; this will be the Official authorized to obligate your organization and sign the resulting Subcontract:

Name

Title

Organization

Address Line 1

Address Line 2

City, State, and ZIP Code

Phone:

Email:

K.2. Offeror Key Personnel

The following individual(s) are considered to be essential to the work being performed hereunder, and shall not be re-assigned, removed or substituted without the concurrence of the Leidos Biomed Subcontracts Administrator:

Name	Title	Email Address

K.3. Offeror Invoice Representative

The following individual is the designated representative to submit invoices:

Name

Title

Organization

Address Line 1

Address Line 2

City, State, and ZIP Code

Phone:

Email:

K.3.a. Offeror Invoice Remittance Address

Organization

Address Line 1

Address Line 2

City, State, and ZIP Code

K.4. Offeror Regulatory Affairs Representative

The following individual is the designated representative handling all matters pertaining to Regulatory Affairs:

Name

Title

Organization

Address Line 1

Address Line 2

City, State, and ZIP Code

Phone:

Email:

L. Offer Signature

By signing of this document, I hereby affirm that I am duly authorized on behalf of my organization to submit this offer and all information including Subcontractor's Representations and Certifications submitted to be accurate and complete.

By:

Title:

Signature:

Date:

Attachment 1: Statement of Work

A. Background

A.1. General

Leidos Biomedical Research, Inc. provides operational and technical support to the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC). Operational and technical support involves the execution of projects sponsored by the National Cancer Institute (NCI) and Department of Energy (DOE). As part of this effort, the Subcontractors shall provide direct support and work products to the IMPROVE activity with the expectation that all work products shall be made freely available in a timely manner**.** The Subcontractors will be expected to work collaboratively with other subcontractors awarded under this program, as well as with the sponsoring organizations and subcontractors awarded under other parts of the IMPROVE activity.

A.2. Project Background

In 2021, NCI and DOE initiated the "Innovative Methodologies and New Data for Predictive Oncology Model Evaluation" (IMPROVE) project, which is intended to build upon what was learned from earlier investments in tumor therapeutic response prediction and support an engagement model with the broader cancer research community. IMPROVE has two related goals, 1) development of semi-automatic protocols for comparing deep learning models for cancer therapeutic response and identifying model attributes that contribute to prediction performance with the goal of IMPROVING future models, and 2) development of protocols for designing drug screening experiments to generate data explicitly aimed at IMPROVING deep learning model performance.

While considerable progress has been made in the last decade in the formulation and training of deep learning models for predicting tumor therapeutic response, there is not a common set of well-documented and well-characterized approaches to preprocessing data for training, selecting the best model architecture, choosing learning parameters, and measuring model performance. Therefore, it is difficult to compare new modelling results in the literature with those from previous studies due to a) different choices of data filtering, encoding, and normalization, and b) different choices of model architectures and model performance metrics, and c) lack of community accepted benchmark data sets. There is a lack of well-curated and standardized training and testing datasets and lack of broadly accepted data preprocessing methods for both tumors associated data and representations of therapies, which makes it difficult to recognize and understand new innovations in data driven models of therapeutic response.

To address gaps associated with the lack of a robust model comparison framework and benchmark data sets, a team from the Department of Energy's Argonne National Laboratory (ANL) and the National Cancer Institute's Frederick National Laboratory for Cancer Research (FNL), hereafter referred to as the IMPROVE NCI-DOE team, and successful offers will provide open implementations of comparison protocols, reference models, test and validation data sets to systematically compare models and modeling approaches. The overall goal is an open, generalizable, and extensible framework for comparing and improving AI models (primarily Deep Learning models) of tumor therapy response in cancer model systems. Additional goals include:

- Evaluating data types in relationship to their cost and patient impact relative to its contribution to model performance
- Evaluating and determining best practices based on existing methods and developing new methods for comparing models, such as methods that consider interpretability, learning capacity, generalizability, stability, and related factors
- Understanding the effects of different data, data preprocessing methods, and model architectures on models
- Generating hypotheses to improve tumor subtyping, define new therapeutic targets, elucidate novel mechanisms of action, and generating other biological hypotheses derived from the machine learning results

This RFP focuses on **IMPROVE Aim 1—IMPROVE Model Comparison:**

- Development of semi-automatic protocols for comparing cancer therapeutic response deep learning models and identifying model attributes that contribute to prediction performance with the goal of IMPROVING future models

Intended outcome

- Award multiple subcontracts to fund extramural research entities to create the **Collaborative Core Modeling Group** (CCMG).
- The CCMG will work collaboratively with the IMPROVE NCI-DOE team at ANL and FNL to produce and test state-of-the-art deep learning modeling approaches for multiple cancer use cases.
- *NOTE: A separate RFI/RFP will be issued in the future for Aim 2-Data Generation*

B. Scope of Work

B.1. Technical Program Support.

The goal of this activity is for the CCMG to develop and apply state-of-the-art computational approaches for comparing deep learning methods for multiple use cases, including but not limited to:

- Predictive oncology scenarios oriented toward recommending therapies and therapy combinations for specific cancer (sub)types to optimize the patient outcome based on clinical objections: remission, debulking, mean survival, and other appropriate metrics. (Demonstrating generalization in tumor space)
- Therapeutic development scenarios in which models are used as proxies for efficacy models in artificial intelligence-driven therapeutic design systems (demonstrating generalization in the therapeutic space)
- Models that can be used to identify novel biological hypotheses to advance cancer research (e.g., models that advance causal inference and integration of mechanistic understanding)

The CCMG will advise the ANL team on the generation of data for the expressed purpose of training, testing, and improving AI models. The CCMG will be given a defined menu of data types available and a

fixed budget for generating the data. This activity will contribute to IMPROVE Aim 2, but actual generation of the data is out of scope for this RFP.
It is expected that offerors will participate in all tasks in this RFP and any proposal that does not cover all tasks in its response will be deemed technically unacceptable and will not be scored.

Task 1 – Project Coordination: Resource and Model Review and Scoping

This involves but is not limited to the following tasks:

a) The initial review of the existing overall organizational structure, open implementations of comparison protocols, reference models, test and validation data sets, large-scale computing resources, and the mathematics, statistical and software infrastructure to systematically compare models and modeling approaches that have already been developed by the IMPROVE NCI-DOE team.

b) In conjunction with the IMPROVE NCI-DOE team and other CCMG members, identify patient-derived models of cancers and select therapies (approved or experimental) for data collection. The actual selection will be made by the IMPROVE NCI-DOE team and will incorporate the feedback from the entire CCMG to best leverage the expertise of the CCMG members, available models and data, and current data generation technologies.

c) In conjunction with the IMPROVE NCI-DOE team and other CCMG members, identify which models can likely be improved to predict outcome of therapeutic interventions based on the subsets of cancers and therapeutics as well as the available data for testing and training. The actual selection will be defined by the IMPROVE NCI-DOE team and will incorporate the feedback from the entire CCMG.

d) Participate in a bi-monthly (maximum 6 per year) coordination meeting to assess and adjust priorities related to all Tasks.

Task 2 - Model Curation: Identify and Reproduce Published Models.

CCMG groups will work on the curation of different models, using the compute environments specified by the IMPROVE NCI-DOE team. This involves but is not limited to the following tasks:

a) Conduct an ongoing literature survey to identify state-of-the-art deep learning therapeutic response prediction models. Present the candidate models to the IMPROVE NCI-DOE team for inclusion in the comparison study (defined in Task 3).

b) If needed for the model, create a workflow to preprocess the data for model training, testing, and prediction.

c) Curate the data that have been used to train and test the model in the publication.

d) Build the required computational environment to run models and reconstruct the prediction model. Create a computational environment to successfully run the model training scripts.

e) If the pretrained model from publication is available, prepare the scripts/software to run the model in inference mode for evaluating model accuracy and reproducibility with the published data.

f) If the pretrained model from publication is available, prepare the scripts/software to run the model in predict mode for making predictions using new data.

g) Convert computational environment, scripts, and models and containerize to interact with the comparison framework (discussed in Framework Development).

h) Conduct reproducibility studies to generate prediction outcomes using the reconstructed prediction model (and the pretrained model if available); to recapitulate key results from publication; and to validate the scripts, model training protocols, and data.

Task 3 – Comparison Study: Implement Processes to Compare Deep Learning Therapeutic Response Prediction Models.

The comparison framework is intended to be a single framework developed jointly by the IMPROVE NCI-DOE Team and successful offerors. This includes but is not limited to the following tasks:

a) Participate in the comparison analysis of curated prediction models using the developed framework. The comparison analysis will fully utilize all suitable evaluation metrics, validation schemes, and data included in the framework to investigate the prediction models. The analysis will be conducted periodically during the processes of framework development and model curation. Results and issues encountered in the comparison analysis will help guide model curation and framework development.

b) Summarize model evaluation and comparison results. Identify the model attributes that lead to the performance difference between models, which can be used to guide future model development and data generation.

c) Prepare slides and reports for potential conference presentations and publications.

d) Assist in the generation of an annual report published in a peer-reviewed journal that covers the results of the comparisons.

Task 4 – Hackathons and Community Engagement

a) On a minimum standing cadence of 3 times per year, provide content and, if needed personnel such as speakers, presenters, and experts for Hackathons and other community engagement activities.

b) As needed serve as judges/reviewers for community-facing activities.

Task 5 – Model Improvement: Improve Models Using Additional Data to Boost Prediction Performance and Translatability.

The Level of Effort (LOE) for this activity will prioritized by the IMPROVE NCI-DOE team and will be secondary to tasks 1 through 4. This task involves but is not limited to the following tasks that will be conducted after the working comparison framework is in place:

a) Design and implement suitable transfer learning approaches to improve curated models using additional data. Most existing therapeutic response prediction models are built using therapeutic screening data on immortalized cancer cell lines. The main purpose of model improvement is to boost its prediction performance on patient data and patient-derived cancer models. Examples of patient-derived cancer models are patient-derived organoids (PDOs), xenografts (PDXs), and primary cell lines (PDCs). Suitable transfer learning approaches need to be implemented to utilize the data generated by the Aim 2 activity for updating the prediction models. The updated prediction models are expected to show an improved prediction performance for patients and patient-derived models. The model improvement can also target performance boosting for specific cancer (sub)types or therapeutic types.

C. Conformance and Compliance: Program Policies and Practices

C.1. Compliance with Section 508 Policies

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this subcontract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site (http://www.hhs.gov/web/508/contracting/technology/vendors.html).

D. Deliverables

The following table contains a list of deliverables with notation of due dates. All days identified are intended to be normal business days unless otherwise specified. The Offeror may suggest an alternative due date for any or all deliverables in their offer. The final schedule will be agreed to by the Leidos Biomed Technical Project Manager (TPM) and the Offeror based on the Offeror's proposed cost and proposed delivery schedule.

D.1. Deliverable Summary and Due Dates

Deliverable	Due Date
Monthly Technical Status Report	On or before the 5th of each calendar month
Monthly Financial Status Report	On or before the 10th of each calendar month
Model Deposition for Verification and Public Release (Includes documentation and metadata related to function, use, and education)	When ready for distribution, all model transfer must be completed as requested by the IMPROVE NCI-DOE team and prior to the end of the contract.
Moonshot Task Order Activity Report	On or before the 15th of August 2022
Project Summary Report	Within 30 days of the end of the subcontract

D.2. Deliverable Descriptions and Acceptance Criteria

D.2.a. General Acceptance Criteria

In addition to specific acceptance criteria listed above, general quality measures, as set forth below, will be applied to each deliverable received from the Offeror under this Statement of Work.

- Accuracy – Deliverables shall be accurate in presentation, technical content, and adherence to accepted elements of style.
- Clarity – Deliverables shall be clear and concise. Any/all diagrams shall be easy to understand and be relevant to the supporting narrative.
- Consistency to Requirements – All deliverables must satisfy the requirements of this Statement of Work.
- Timeliness – Deliverables shall be submitted on or before the due date specified in this Statement of Work or the PMP or submitted in accordance with a later scheduled date determined by Leidos Biomed.

E. Reporting Requirements

E.1. Monthly Technical Status Report

Offerors shall submit Monthly Status Reports documenting the efforts performed in the completion of each task. The Monthly Status Report is due on or before the 5th of the month. **The required information must be submitted on or before the time of invoice, otherwise invoice payment may be delayed.**

It is expected that the Monthly Status Report will include, but not be limited to:

- Offeror Name and Address
- Name of Person Submitting the Monthly Status Report
- Subcontract Number
- Monthly Status Report Date
- Period Covered by the Monthly Status Report
- Program status, to include objectives met, work completed and work outstanding
- Notable achievements
- Issues or obstacles impeding progress and recommended solutions
- Status of deliverables/milestones
- Issues and resolutions
- Resource planning/status
- Description of work completed and plans for next month including anticipated travel/planned time off

E.2. Monthly Financial Status Report

The Subcontractor shall prepare the Monthly Financial Status Report using the Monthly Financial Status Report template due on or before the 10th of each month. It is expected that this report will include, but not be limited to:

- Total monthly and cumulative hours worked by resource and by subproject
- Total monthly and cumulative costs by resource and by subcontract
- Estimates to Complete (ETCs) including estimated accruals for this effort
- Estimate at Completion (EAC) for this effort
- Changes to the expected monthly burn rate for the duration of this effort
- Total monthly hours worked by resource and by program support area as stated in the SOW.

E.3. Model Deposition (Includes documentation and metadata related to function, use, and education)

- Models for Verification
    - Once a model is selected for curation (Task 2) a placeholder entry will be created in NCI's Predictive Oncology Model and Data Clearinghouse (MoDaC), https://modac.cancer.gov/ or another specified location.
    - Models (associated documentation and metadata must comply with the Findable, Accessible, Interoperable, and Reusable (FAIR)-principles as well the MoDaC deposition standard related to function, completeness, use, and interpretation) will be uploaded to MoDaC for verification and distribution once they demonstrate that they are reproducible according to the metrics of the reproducibility study defined in Task 2.
    - If required, models (with associated documentation and metadata related to function, use, and education) will be re-uploaded to MoDaC once they are retrained/improved and the proper versioning information is provided.
    - If a model cannot be reproduced or is otherwise excluded from the Comparison Study (Task 3) the "in progress" materials and notes about the effort will be made available via MoDaC so lessons learned can be made public.
- Models for Public Release
    - Once models are verified, they will be released publicly through the normal NCI-DOE Collaboration capability transfer process for use by the broader research community.

E.4. Moonshot Task Order Activity Report

It is expected that the Moonshot Task Order Activity Report will include, but not be limited to:

- Offeror Name and Address
- Name of Person Submitting the Report
- Subcontract Number
- Report Date
- Period Covered by the Report
- A comprehensive Summary of Work performed during reporting period

E.5. Project Summary Report

Offeror shall submit a Final Report within 30 days of completion.

It is expected that the Final Report will include, but not be limited to:

- Offeror Name and Address
- Name of Person Submitting the Final Report
- Subcontract Number
- Final Report Date
- Period Covered by the Final Report
- A comprehensive Summary of Work performed during the project
- A summary of Lessons Learned

F. Place of Performance

The Subcontractor shall conduct the work at an appropriate location based on current NCI Policies.

G. Government Furnished Data, Materials, or Equipment

The NCI will not furnish any computer and workstation equipment**.**

Attachment 2: Price Template

Price Proposal Form

Item/ MS #	Title/Description/Requirements	Unit of Measure	Qty	Unit Price	Extended Amount
				TOTAL PRICE	

Note: MS means Milestone