Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

IMPORTANT NOTES TO READ BEFORE PROCEEDING

Rising Tide Foundation for Clinical Cancer Research ("Rising Tide") and LUNGevity Foundation ("LUNGevity") are partnering to issue an RFA to study how shared mechanisms of resistance can be targeted in oncogene-driven lung cancers.

Rising Tide and LUNGevity Foundation advise applicants to read the entire RFA, including eligibility requirements and other terms and conditions, before starting an application. Any applicant who is deemed ineligible for this award and/or does not follow the instructions for preparing the application will be disqualified and the application not reviewed.

The Rising Tide/LUNGevity Award Program to Target Mechanisms of Resistance uses a **two-step application process**. An applicant must first submit a letter of intent (LOI). Only a subset of applicants will be invited to submit a full application after the LOIs are reviewed. The application process will be managed through proposalCENTRAL.

Important Dates:

- February 16, 2024: Letter of Intent (LOI) deadline
- May 15, 2024: Full applications due from invited applicants
- Late Summer 2024: Award notifications made
- November 1, 2024: Award begins

Detailed instructions for applying for this award begin on page 8.

RISING TIDE FOUNDATION

Rising Tide Group is an organization with a strong philanthropic mission. While based in Schaffhausen Switzerland, the Foundation is truly global in its reach and activities. Our philanthropic work is organized in two entities – the Rising Tide Foundation (RTF) and the Rising Tide Foundation for Clinical Cancer Research (RTFCCR). Both are charitable, non-profit organizations established in 2010. The Rising Tide GmbH is the service company for both foundations and responsible for the promotion and the offering of philanthropic services of the foundations, for the financial prosperity and operative well-being of the organizations, and for the sustainable income generation. Our philanthropic mission is very close to the heart of our founder and chairman who was not only personally impacted by his mother's and grandmother's experiences with cancer but is also deeply rooted in an empowerment philosophy. The Foundation was created with the belief that those who are most vulnerable to critical issues and who are willing and ready to take on responsibility are the most effective agents of change and should contribute as members of society with a spirit of freedom to solve their own problems. For more information about Rising Tide, please visit https://www.risingtide-foundation.org/.

LUNGEVITY FOUNDATION

LUNGevity Foundation is a 501(c)(3) philanthropy specifically focused on funding research for the early detection and effective treatment of lung cancer. LUNGevity's mission is to improve mortality rates of lung cancer patients through the development of protocols and tools for early detection of lung cancer, early intervention in the disease progression, and treatments,

including targeted therapy and immunotherapy. LUNGevity focuses on translational science. For more information about LUNGevity Foundation, please visit www.LUNGevity.org.

FUNDING OPPORTUNITY DESCRIPTION

Goal of the program

To fund high-impact interventional clinical trials that seek to develop therapeutic strategies targeting shared mechanisms of resistance in oncogene-driven lung adenocarcinoma.

Overview

Increased understanding of the molecular heterogeneity of lung cancer has remarkably changed the therapeutic landscape of non-small cell lung cancer (NSCLC), a subtype of lung cancer. Around 85% of all lung cancer cases are NSCLC, of which lung adenocarcinoma (LUAD) is the predominant subtype (40% of all lung cancers).[1,2] Now, the molecular sub-type of LUAD is a major determinant of the type of treatment a patient will receive, as against histologic classification.[3] As of July 2022, nine different molecular sub-types of lung adenocarcinoma (LUAD), characterized by different biomarkers, have matched FDA-approved targeted therapies, the majority of which are tyrosine kinase inhibitors. These biomarkers include ALK fusions, BRAFV600E mutation, EGFR mutations (sensitizing EGFR mutations), EGFR Exon 20 insertions, KRAS G12C mutation, MET Exon 14 skipping mutations, NTRK fusions, RET fusions, and ROS1 fusions; and are typically detected in DNA/RNA NGS panels. Approximately 45%-50% of LUAD have these known biomarkers and respond to targeted therapies.[3,4] The number is higher in patients of Asian descent.[3] Despite the initial success seen in patients treated with targeted therapies against these biomarkers, the cancers typically develop acquired resistance and recurrence is almost inevitable.[4]

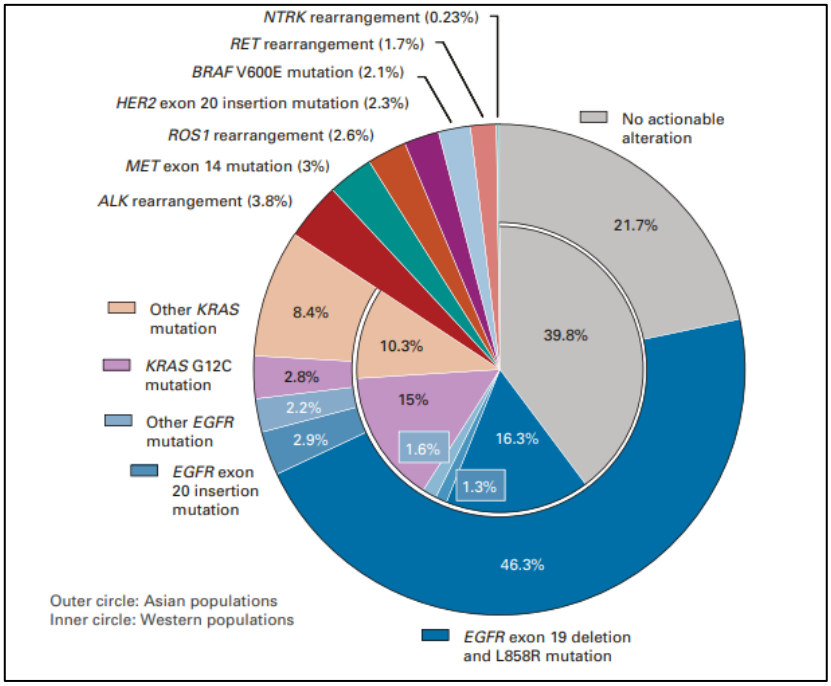

Figure 1: Targetable oncogenic drivers in LUAD[3]

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

Acquired resistance can be either on-target or off-target mechanisms. An increase in profiling of tumor samples upon progression on targeted therapies is shedding light on both on- and off-target mechanisms of resistances.[5]

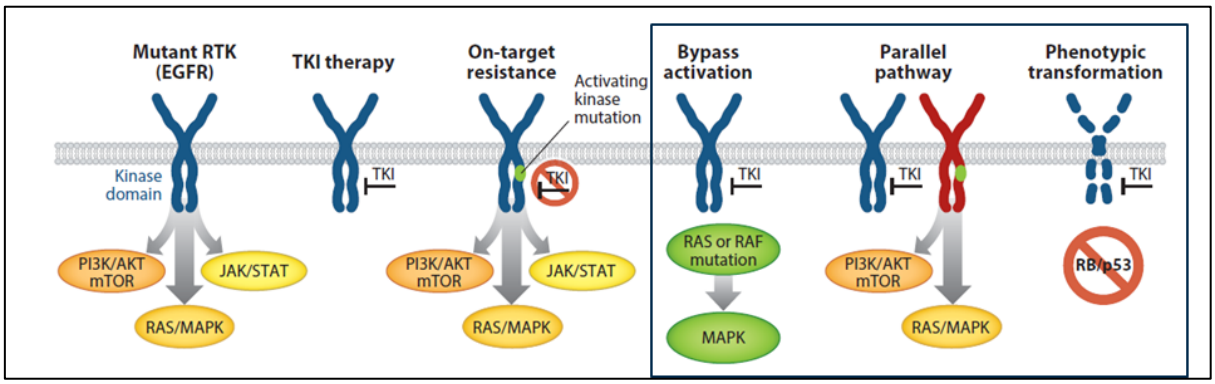

Figure 2: On-target and off-target (in black box) mechanisms of resistance in oncogene-driven LUAD[5]

Some shared or common pathways of off-target mechanisms across the different oncogene-driven LUADs include:

- Bypass signaling through common signaling nodes such as the ERB/HER family or the RAS/RAF pathway[5,6]
- Histologic or phenotypic transformation of LUAD into other sub-types of lung cancer such as small cell lung cancer, squamous cell lung cancer, or large cell lung cancer.[5,6]

Resistance Mechanisms	MET	EGFR/ HER2/ HER3	AXL	IGF1-R	FGFR 1/2/3	NTRK 1/2/3	KIT	RAS (KRAS, NRAS)	BRAF	MAP2K1
Therapeutic Targets	ALK	ALK	ALK	ALK	EGFR	EGFR	ALK	ALK	ALK	ALK
	EGFR	BRAF	BRAF				ROS1	EGFR	EGFR	BRAF
	NTRK	EGFR	EGFR					NTRK	NTRK	NTRK
		NTRK	RET					RET		
		RET						ROS1		
		ROS1								

Figure 3: Off-target mechanisms of resistance in oncogene-driven LUAD converge in common signaling nodes (highlighted in red boxes)[6]

Rising Tide and **LUNGevity** are partnering to support research that aims to understand how we can target shared mechanisms of off-target resistance seen across the different oncogene-driven LUAD. The rationale for focusing on shared off-target mechanisms of resistance is as follows:

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

- Several pharmaceutical companies are developing next-generation inhibitors to target **on-target mechanisms** of resistance[7]
- Given that shared off-target mechanisms converge on common signaling nodes that already have drugs in development or approved in other indications, a concerted focus on off-target mechanisms will allow for repurposing of these drugs
- Off-target mechanisms of resistance are highly dependent on the tyrosine kinase inhibitor used. Targeting these shared mechanisms of resistance will address the **What's next**? question for a high proportion of this growing population of patients with oncogene-driven LUAD.

AWARD PROGRAM REQUIREMENTS

Funded project(s) are expected to have a direct clinical impact on patients with oncogene-driven lung adenocarcinoma (LUAD) and will need to address shared mechanisms across 3-4 oncogene driven LUADs. Projects that focus on one type of oncogene-driven LUAD will not be funded through this mechanism**.**

Both LUNGevity and Rising Tide Foundation for Clinical Cancer Research highly value the involvement of patients from the very beginning (design) phase of a clinical trial, therefore a Patient Involvement Plan (PIP) is a required component of each applications. Details on how to write a PIP will be available in this document.

The award totaling up to $1,500,000 USD ($750,000 from LUNGevity and $750,000 from Rising Tide) will be funded for a duration up to 3 years. We anticipate funding at least one award through this mechanism. The Rising Tide/LUNGevity award will NOT cover the total cost of a trial.

Scientific scope of projects

Successful proposals are expected to be interventional clinical trials aimed at addressing the problem of shared mechanisms of resistance across oncogene-driven LUAD by targeting them using novel pharmaceutical agents (monotherapies or combination therapies). **We aim to fund those projects that would otherwise not be accomplished without philanthropic support**. An example of such a project is a proof-of-concept Phase 1 clinical trial **or adding additional arms to an existing trial** looking at shared mechanisms of resistance.

Suggested areas of investigation may include, but are not limited to, the following:

1. ***Combatting mechanisms of persistence***: Interventional clinical trials that test first-line treatments to combat emergence of off-target mechanisms of resistance by targeting drug tolerant persistent cells.
2. ***Combatting mechanisms of resistance:***
   - Interventional clinical trials that aim to understand novel treatment options such as new Phase 1 umbrella clinical trial or a trial design that uses an adaptive platform. A novel treatment option may be a monotherapy option or a rationally designed combination approach that includes repurposing drugs.
   - New therapy arms using repurposed drugs or novel agents for an existing clinical trial. If studies are proposed in this category, proof of IRB approval of protocol at the time of grant activation will be required.

- Interventional clinical trials investigating molecular predictors of acquired resistance at the time of diagnosis and implementing interventional strategies to overcome these mechanisms of resistance.
- Correlative studies of interventional clinical trials aimed at investigating molecular mechanism of resistance across multiple oncogene-driven LUADs. If studies are proposed in this category, proof of access to adequate samples will be required.

The following criteria **must** be met for the proposed clinical trial:

1. Clinical trials need to be an interventional trial with potential to lead directly to improved outcomes. If an investigational trial is not a part of the initial proposal, the applicants must clearly demonstrate/explain how the proposed project will lead to such a trial and within what timeframe.

2. Pharmaceutical agents can be approved drugs being used in an off-label fashion approved for this indication, or under development

3. Open for early stage first in human clinical trials to late-stage clinical trials (Phase 1, 2 and 3) where creation of a patient-initiated protocol is possible (described later in guidelines for patient engagement)

4. Clinical trials should serve patients interests with primary clinical endpoints Trials may have biological or translational secondary endpoints

5. If correlative studies are essential to the development of the interventional trial, the applicant must clearly describe how the correlative studies will lead to an interventional trial with clinical endpoints.

6. Patient engagement is a critical component of this application. Detailed instructions are provided in this document.

The research questions listed above are meant to serve as examples and are by no means restrictive.

Note: Clinical trials testing immunotherapies need to be discussed with Rising Tide/LUNGevity before applying since their applicability in the treatment of oncogene-driven LUAD is limited.

Final selection will be contingent on scientific review and availability of funds. If you have any questions, please contact us to clarify the scope of your project.

Successful applicants are required to share their research progress with the Rising Tide Foundation and the LUNGevity teams (Scientific Advisory Board, other reviewers, and other awardees) annually at the LUNGevity science meeting. Members of Rising Tide Foundation will participate in this meeting.

Eligibility
Education and Experience: At the time of the grant term, the applicant, who must be a principal investigator for the proposed research, must:

1) hold a doctoral degree and faculty appointment (or equivalent) with an academic institution, including research institutions that are not formally associated with a university
2) have completed a postdoctoral training fellowship.

An applicant may be at any level of research experience and must be an independent, self-directed researcher for whom their institution must provide space and other resources customary for independent investigators. The application must convey the commitment of the institution to the applicant and the proposed research activities. An applicant with an existing Rising Tide Foundation Award or a LUNGevity award that would be concurrent with Rising Tide/LUNGevity Award is not precluded from applying.

Team Award Requirement: This is a team award and at least two institutions are required to be involved right from the LOI stage. One institution may serve as the primary institution. We recommend identifying one US and one non-US institution to develop the team. Please reach out to us if you have any questions about the team requirement.

Geographical Restriction: As noted above, international teams are **highly recommended**, and the Award Program does not have any geographical restrictions.

For US applicants only: Applicants are **not** required to be U.S. citizens or to be employed by a U.S. institution. **At the time of application, if an applicant is employed by a U.S. institution**, they must be a United States citizen or a foreign national holding one of the following visa immigration statuses: permanent resident (Green Card), exchange visitor (J-1), temporary worker in a specialty occupation (H-1, H-1B), Canadian or Mexican citizen engaging in professional activities (TC or TN), or temporary worker with extraordinary abilities in the sciences (O-1). This applicant/awardee must be employed by a U.S. institution throughout the duration of the award term.

The application must be submitted in English.

AWARD INFORMATION

Award Structure

Investigators may receive up to $1,500,000, over three years. No more than 25% of the requested budget may be used for an investigator's salary and/or fringe benefits. Overhead/indirect costs are not permitted.

Award funds may be used for the salary and fringe benefit costs of personnel other than the applicant. Fringe benefit costs may only be expended upon the stipulation that they cannot be obtained from another source.

Allowable costs for clinical trials include: expenses related to subject recruitment (such as participation incentives, subject remuneration, phlebotomy charges, etc.), clinical laboratory analyses of human subjects or their samples (such as clinical laboratory assays, imaging charges, etc.), and correlative studies. While the award may be used to help with operational

costs, the investigator is required to procure funding to cover the remaining cost of the trial. **Drug costs will not be covered.**

This award is subject to annual reviews and may be granted for up to three years.

Award Selection
Final selection of the project to be funded will be contingent on scientific review and availability of funds.

Some of the factors considered when reviewing applications include:

- Innovation – Does the project address a shared mechanism of resistance in LUAD?
- Scientific merit and feasibility of the research plan, including partnerships
- Impact – How will the research findings from the project move to the clinic within a reasonable time frame and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
- Study design and its burden on patient participation, i.e., how difficult is it for patients to participate in the proposed study? We recommend study designs that support the inclusion of a diverse group of patients.
- Research environment – Does the applicant have access to institutional resources required for the successful completion of the proposed project?
- Appropriateness of the requested budget to complete the proposed research project/Other sources of funding, including potential overlap with proposed project. Other factors used to evaluate the budget include total cost of the trial, the amount requested and the plan to secure the remaining funds to ensure that the trial can be completed.
- Patient engagement activities: How patient partners will be actively engaged in the study from the development of research questions through dissemination of study results. Specific guidance for preparing a Patient Engagement Plan can be found here.

OTHER TERMS AND CONDITIONS

Once an award selection is made, LUNGevity Foundation and Rising Tide Foundation will each issue a separate funding award agreement that would cover 50% of the total awarded budget. The team will monitor progress of the study using a milestone-based reporting process, where three written reports (financial and scientific progress reports) are required annually detailing progress towards achieving milestones. A financial and scientific progress report will be due within 60 days of completion of the grant.

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

APPLICATION INSTRUCTIONS AND TIMELINE

Applicants will be allowed to submit their letter of intent (LOI) beginning January 8, 2024.

Letter of Intent (LOI)
The letter of intent **must** include a narrative that contains:

1. **Rationale** for the project with details on how the project will impact clinical care of oncogene-driven LUAD

2. Planned **specific aims** (may be modified slightly in the full application)

3. Brief statement of the **overall experimental approach**

4. Brief statement describing the **clinical context** in which the therapeutic strategy will be used

5. Brief statement of the **quantitative metrics/performance** that the approach should achieve to show clinical utility

6. **Patient engagement plan table** – Before filling this table, please read the instructions in **Appendix A**. Please use the table in **Appendix B** to show how patient partners/advocates will be actively engaged in the study from developing research questions through dissemination of results

7. **References**

The narrative should be typed in Arial 11-point type, single-spaced, with .5" margins. It should not exceed a total of **three pages**, including the references. **Your LOI will not be considered if these instructions are not followed.**

US applicants should include an NIH biosketch for the principal investigator and co-principal investigators only. Non-US applicants should include a 2 page CV with their application. Note that "other support" should include the value of the support.

No budget information or other supporting materials should be included with the LOI. A sponsoring institution signature is not required.

Templates and detailed instructions can be found at https://proposalCENTRAL.com.

Letters of Intent are due **by February 16, 2024 (11:59 pm EST)**, via proposalCENTRAL. Extensions will not be given. Once an LOI has been submitted it cannot be changed.

Applicants will be notified by email no later than **March 25, 2024** whether they will be invited to submit a full application. Rising Tide/LUNGevity will **not** provide feedback regarding results of the review of any Letter of Intent submitted.

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

Full Application

Only invited applicants may prepare and submit a full application. Instructions for how to proceed will accompany the invitation. Among other materials, the full application must include:

• A narrative to include these nine components and references:

1. **Lay Abstract** that explains your project completely in lay terms that will be clear to individuals who do not have a scientific background. Specific details on how the project will have a near-term impact on the clinical outcome of patients with oncogene-driven LUAD should be included.
2. **Scientific Abstract** that would be appropriate for a reviewer of a peer-review journal
3. **Background**: Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
4. **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
5. **Specific Aims:** Concisely explain the project's specific aims.
6. **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Please include a detailed sample size justification for the proposed clinical trial and any statistical analyses you propose to use. Also, clearly describe impact on patient participation (for example, number and frequency of blood draws and biopsies, number of clinical visits, etc.)
7. **Patient Engagement Activities**: Based on the Patient Engagement Table provided in the LOI, we will ask you details about your engagement activities.
8. **Budget with budget justification**: Detailed budget will need to be provided, included total cost of the clinical trial and how funds (separate from the RTFFCR/LUNGevity award) will be procured to complete the trial. In your budget, please also include how funds will be used for patient engagement activities, including funds for advocates to travel to research meetings and conferences.
9. **Patient impact statement** – How will the research findings from the project move to the clinic within a reasonable time frame and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
10. **Protocol/Draft protocol**: Please submit a DRAFT protocol for the proposed trial, even if it has not been approved by your institution's IRB.
11. **Statistical analysis plan:** A detailed statistical analysis plan is required for all applications and is limited to 1 single-spaced page. The analysis plan should define the primary objectives, study design, and planned analyses supporting the study hypotheses. Justification of the proposed sample size or number of patient samples to be analyzed should be stated and include all parameters required for calculation: the type I error rate, power, and target effect size. Detail regarding analysis methods, groups to be compared, and other assumptions made (for example, regarding accrual rates, follow up, etc.) should also be included. Ideally, the applicant will collaborate with a biostatistician on their grant proposal, including this analysis plan. In the event that methods from other quantitative sciences are planned (for example, bioinformatics or computational biology), it is recommended that the applicant also collaborate with experts from those respective fields to develop their application and analysis plan.
12. **References**

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

The narrative should be in English, typed in Arial 11-point type, single-spaced, with .5" margins, including references. The narrative should not exceed a total of **11 pages**, **(10 pages for the narrative and one page for the statistical analysis plan.** The references should also be included within the 11 pages.

- NIH **biosketches** of all PIs and Key Personnel (both current and pending support). The sketches should be limited to four pages each.

- **Budget information** by six-month period, along with a justification

- **Other support**, including current and pending, is only required for the PI and any co-Pis. The value of the support should be included.

- Do **not** include reprints of your previous publications.

Templates and more detailed instructions for all of the above materials and any other materials that must be included can be found at https://proposalCENTRAL.com.

Applicants are required to electronically submit the full application by **May 15, 2024 (11:59 PM EST)**, via proposalCENTRAL: https://proposalCENTRAL.com. Extensions will not be given. Once a full application has been submitted electronically, it cannot be changed.

Applicants will be notified by email in Late Summer 2024 whether they will receive an award. Rising Tide/LUNGevity will provide results of the peer review process for full applications.

Awardees will receive formal agreement documents at the time of or soon after award notification. These must be signed by both the awardee and an authorized representative of the sponsoring institution and then returned to LUNGevity before any funds will be released.

APPLICATION ASSISTANCE

For answers to questions regarding programs, eligibility, policies, terms and conditions, or instructions for the letter of intent or full application, please contact:

Upal Basu Roy
Executive Director of Research
ubasuroy@LUNGevity.org

Alexandre Costa Alencar
Senior Scientific Program Manager
alexandre.alencar@risingtide.ch

For help with the proposalCENTRAL electronic application process, please contact:
Help Desk at proposalCENTRAL
pcsupport@altum.com
1-800-875-2562

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

REFERENCES

1. Clark SB, Alsubait S. Non Small Cell Lung Cancer. In: *StatPearls.* Treasure Island (FL)2022.
2. Myers DJ, Wallen JM. Lung Adenocarcinoma. In: *StatPearls.* Treasure Island (FL)2022.
3. Tan AC, Tan DSW. Targeted Therapies for Lung Cancer Patients With Oncogenic Driver Molecular Alterations. *J Clin Oncol.* 2022;40(6):611-625.
4. Thai AA, Solomon BJ, Sequist LV, Gainor JF, Heist RS. Lung cancer. *Lancet.* 2021;398(10299):535-554.
5. Tulpule A, Bivona TG. Acquired Resistance in Lung Cancer. *Annual Review of Cancer Biology.* 2020;4(1):279-297.
6. Doebele RC. Acquired Resistance Is Oncogene and Drug Agnostic. *Cancer Cell.* 2019;36(4):347-349.
7. Deb D, Moore AC, Roy UB. The 2021 Global Lung Cancer Therapy Landscape. *J Thorac Oncol.* 2022;17(7):931-936.

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

Appendix A

GUIDANCE FOR PLANNING YOUR PATIENT ENGAGEMENT IN RESEARCH

Early involvement of Patient Partners, based on co-design principles allows a better formulation of relevant research questions, more credibility of the knowledge produced, identifying, and solving potential challenges faced during the trial, and better application of outcomes to specific contexts.

Here is a checklist to help you plan Patient Engagement and complete our Patient Engagement Plan table required to be submitted as part of the Letter Of Intent. It encompasses points that should be considered for the application phase, during the implementation of the project, and beyond the project.

Before the project starts

- Patient Engagement is planned across the entire project lifecycle
- The most appropriate Patient Engagement model is selected
- The appropriate Patient Partners are involved early in formulating the concept, hypothesis
- Appropriate budget for patient engagement activities and compensation of Patient Partners is reflected in the Patient Engagement Plan and the overall grant budget request

During the project

- Assessment of needs of trial participants by Patient Partners is included
- Adaptation of trial and procedures where necessary to meet trial participants' needs
- Assessment of the impact of patient engagement in your project at mid-term and at the end of the project is considered

Beyond the project

- Communication and dissemination of study outcomes with patient / public partners is planned after project end
- Collaboration with patient community on trial outcomes is planned

For more information, please refer to: http://synapse.pfmd.org/resources/considerations-guide-to-implementing-patient-centric-initiatives-in-health-care-product-development/download

Note: Please consider the choice of your patient advocates that you engage in order to select the ones who can best add value to this project

CHOICE OF MODEL OF PATIENT ENGAGEMENT IN RESEARCH PROJECTS

Research teams should think carefully about the activities across the whole project lifecycle that the Patient Partners could undertake. Short term activities are easy to define upfront, but it is more challenging to think about sustained involvement across the entire project.
Therefore, depending on the research project, it is important to think about the most applicable role of a Patient Partner for contributing in a clinical research project:

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

Patient role	Examples	Engagement level
Team Member role	• Patients provide a priori and continuous consultation on outcomes of importance, study design, etc. • Patients are paid investigators or consultants • Patients have a governance role – "a seat at the table"	High
Advisor role	• Patients serve as advisory committee members or provide a priori consultation on outcomes of importance and study design, but have no leadership role or governance authority	Moderate
Reactor role	• Patient input is collected distally through surveys, focus groups or interviews, but patients are not consulted directly or a priori on such things as study design and outcomes of importance • Patients are asked to react to what has been put before them rather than being the origin of the concepts of interest	Low

PATIENT ENGAGEMENT PLAN

We require you to submit a "Patient Engagement Plan" as part of your LOI and Full Application. The plan should describe Patient Engagement processes during the generation of the project application as well as during the implementation of your project. It describes engagement e.g., how you engaged with the patient community when your research question was defined, while the proposal is written, when it is being submitted and resubmitted, and which patient engagement model you chose for the implementation of your project.

When developing your project budget, please make sure that adequate and realistic resources for Patient Engagement are reflected in the Patient Engagement Plan and the overall grant budget request. This could include e.g. appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g. travel expenses and meeting venue costs).

Different phases of research will need different activities to ensure patient engagement is implemented in the way defined in this document, *for example Phase I first in human studies may require a different approach than other studies.*

For the LOI, please use the Table in Appendix B to propose your Patient Engagement Plans. For the full application, we will accept different formats of patient engagement plan, as long as:

- Activities proposed are listed and properly described
- Activities proposed are designed for patients and with patients
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

Please be very clear at the outset about what you expect to achieve and what metrics – both quantitative and qualitative – you will use to measure progress against and achievement of both overall research goals and specific patient-centricity goals.

Appendix B

PATIENT ENGAGEMENT IN RESEARCH

The checklist below is to help you plan Patient Engagement and complete our Patient Engagement Plan template required to be submitted with your Letter of Intent.

Before the project starts

- ☐ **Patient Engagement is planned across the entire project lifecycle**
- ☐ **The most appropriate Patient Engagement model is selected**
- ☐ **The appropriate Patient Partners are involved early in formulating the concept, hypothesis**
- ☐ **Appropriate budget for patient engagement activities and compensation of Patient Partners is reflected in the Patient Engagement Plan and the overall grant budget request**

During the project

- ☐ **Assessment of needs of trial participants by Patient Partners is included**
- ☐ **Adaptation of trial and procedures where necessary to meet trial participants' needs**
- ☐ **Assessment of the impact of patient engagement in your project at mid-term and at the end of the project is considered**

Beyond the project

- ☐ **Communication and dissemination activities involving patient / public partners is planned after project end**
- ☐ **Collaboration with patient community on trial outcomes is planned**

PLEASE REFER TO THE FUNDING GUIDELINES FOR FURTHER INFORMATION ON PATIENT ENGAGEMENT MODELS AND PREPARE YOUR PATIENT ENGAGEMENT PLAN ACCORDING TO THE TEMPLATE PROVIDED BELOW

Rising Tide/LUNGevity Team Award
Program to Target Mechanisms of Resistance
2024 Request for Application

PATIENT ENGAGEMENT PLAN

Phase	Activity	Description of patient role	Objectives	Deliverables	Budget
Patient centric design					
During protocol development					
Grant application development and submission					
During the trial					
Dissemination of results					