



ANNOUNCEMENT TITLE	ASTRO-Myovant Sciences-Pfizer Alliance New Combination Therapy Challenge
PROGRAM YEAR	2022
MECHANISM	Advancing-Medicine-Together Scientific Challenges
PA NUMBER	SC-2022-01-MYOV-PFE
GRANTOR	Myovant Sciences-Pfizer Alliance
OPEN DATE	March 29, 2022
PURPOSE	To catalyze new collaborative research opportunities, and to facilitate radiation oncology leadership in scientific discovery with the Myovant Sciences-Pfizer Alliance in the space of multimodality combination therapy.
TERM OF POTENTIAL GRANTOR SUPPORT	Recommended term is up to 5 years. Entries requesting more than 4 years of performance periods must be supported by strong justification and plan(s) for intermediate read outs/outcome measures for progress tracking.
NUMBER OF GRANTS	Up to 3-5 awards as selected by the expert review panel
BUDGET	<ul style="list-style-type: none"> The target budget for each individual project grant is up to US\$500,000 (Total costs, which include both direct and indirect costs). However, individual projects requesting higher amounts will be considered based on scientific merit and funding availability. Overhead (indirect cost) rates of up to 28% of the total proposed project budget are allowed. The amount of the Myovant Sciences-Pfizer Alliance funds for any project will depend upon the expert review panel's (ERP) (also known as the Challenge Judging Panel) evaluation of the proposal and costs involved and will be stated clearly in the approval notification. <p>Funding for the 2022 ASTRO-Myovant Sciences-Pfizer New Combination Therapy Challenge is up to \$2,500,000, across 3-5 projects.</p>
ENTRY DUE DATE	July 18, 2022; 11:59 PM Eastern time (GMT -5)
AWARD NOTIFICATION DATE	Award notification is anticipated in September 2022.
EARLIEST START DATE	December 15, 2022
CHALLENGE STATEMENT/RESEARCH AREAS OF INTEREST	<p>How can prostate cancer treatment be improved with the gonadotropin-releasing hormone (GnRH) receptor antagonist relugolix in patients receiving radiotherapy?</p> <p>Research proposals in the following topic areas are encouraged:</p> <ul style="list-style-type: none"> Use of relugolix with definitive radiotherapy (concomitant/adjuvant/neoadjuvant) in prostate cancer patients with High/Very-High Risk, Unfavorable Intermediate Risk, and Regional disease Use of relugolix with radiotherapy as salvage therapy post treatment with curative intent Concomitant treatment with other oral oncolytics (e.g., ARIs) Synchronous oligometastatic/metastatic and oligoprogressive disease

	<p>Studies of interest may include evaluating the following:</p> <ul style="list-style-type: none"> • Clinical outcomes (i.e., rPFS, MFS, local control, etc.) • Testosterone kinetics • Patient-Reported Outcomes (PROs) • Safety/Adverse Events (AEs) • Compliance/adherence • Translational research such as exploratory biomarkers and mechanistic studies may be considered as part of a clinical trial. <p>Topic areas out-of-scope include:</p> <ul style="list-style-type: none"> • Recurrent oligometastatic disease • Retrospective studies • All other tumor sites • Ex-US studies
GEOGRAPHIC SCOPE	United States
ELIGIBILITY	<p>The general eligibility criteria for this PA are listed in this section.</p> <p>To be eligible:</p> <ul style="list-style-type: none"> • The institution and principal investigator (PI) must be based in the United States. • Only organizations are eligible to receive grants, not individuals nor medical practice groups. • Applicant must be affiliated with a host institution. <p><u>Eligible Organizations</u></p> <p>Higher Education Institutions</p> <ul style="list-style-type: none"> • Public/State Controlled Institutions of Higher Education • Private Institutions of Higher Education <p>Nonprofits Other Than Institutions of Higher Education</p> <ul style="list-style-type: none"> • 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) <p><u>Non-Eligible Organizations</u></p> <p>Foreign Institutions</p> <ul style="list-style-type: none"> • 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. <p><u>Eligible Individuals (Principal Investigators (PIs))</u></p> <p>Multiple PIs are allowed and collaborations mentoring young investigators are encouraged. Both early career and experienced investigators are encouraged to apply and consideration will be given to all proposals meeting the selection criteria.</p>

	<p><u>Degree Requirements and Faculty Appointment</u> At the time of entry, the applicant (PI) must have a medical or postdoctoral degree (MD, PhD, or equivalent). Generally, residents, postdoctoral fellows, or other trainees are not eligible to apply. However, if at the time of entry submission, a trainee has secured an independent faculty position and provided supporting evidence and endorsement from an Eligible Organization which offers the aforementioned independent faculty position, ASTRO can choose to accept the Challenge entry from such a trainee for review, if all other eligibility criteria for such an entry have been satisfied.</p>
<p>COMMITMENT FROM THE CHALLENGE PRINCIPAL INVESTIGATORS (PIs)</p>	<ul style="list-style-type: none"> • <u>Collaborators</u>: Transdisciplinary collaborations are encouraged but the proposed project team must include at least one radiation oncologist. • <u>ASTRO Meetings</u>: If selected for this challenge, the PI will be asked to attend at least one ASTRO Annual Meeting (either virtually or live) and present their research findings at the meeting.
<p>COMMITMENT FROM THE PI'S AFFILIATED ELIGIBLE ORGANIZATION</p>	<ul style="list-style-type: none"> • If awarded, the host institution will act as the fiscal intermediary to interact directly with Pfizer and Myovant. The Institution will administer the funds to the PI and be responsible for satisfying tax withholding, deposit and/or reporting requirements applicable to the payment of the award. The PI will be responsible for individual income taxes. The Institution will be required to provide sufficient additional funds to supplement salaries or supplies as needed for the research project. • Only 1 grant can support the proposed research project. If independent funding is obtained for the same scope of work selected by the challenge the recipient must refuse either this or the competing award(s).
<p>HOW TO APPLY</p>	<ul style="list-style-type: none"> • Please go to www.cybergrants.com/pfizer/Research and sign in. • First-time users should click "Create your password". • [Note: There are individual portals for each grant application type (e.g., knowledge, LOI, research full proposal, and QI full proposal). Please be sure to use the URL above.] • Click the "Start A New Research Grant Application" button. <p>Requirements for submission:</p> <ul style="list-style-type: none"> • For the question "Competitive Grant?" select Yes. • Select the following Competitive Grant Program Name: 2022 ASTRO-Myovant Sciences-Pfizer Alliance New Combination Therapy Challenge • Complete all required sections of the online application. • If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.
<p>CHALLENGE ENTRY SUBMISSION GUIDELINES</p>	<p><u>Submission</u> All entries are due by 11:59 pm U.S. Eastern Time on July 18, 2022. Proposals will not be considered after the deadline. Entries must be submitted online using the Pfizer ISR Grant System</p>

(<https://www.cybergrants.com/pfizer/Research>). Please note that no letter of intent (LOI) will be accepted. PIs will submit a full proposal directly in a single step to be evaluated by the scientific review/judging panel. Prospective researchers who are interested in receiving preliminary and non-decisive feedback on the alignment of any research idea with the Challenge's research areas of interest can contact the program staff at the ASTRO Department of Scientific Affairs (science@astro.org) before the Entry Due Date.

Entry Content

It is critical that applicants follow the instructions. Conformance to the requirements in this PA are required and strictly enforced. Entries that are out of compliance with these instructions may be delayed or not accepted for review.

All materials must be prepared in English, single spaced, using a font size of 11 or 12 points. Smaller text in figures and charts is acceptable, once it is legible when the page is viewed at 100%. Arial or Times New Roman fonts are recommended. A minimum of one-half inch margins must be used on all page borders.

1. **Title Page:** Enter the Project Title and Discipline of Research.
2. **Templates and Instructions:** Download PA and templates.
3. **Enable Other Users to Access this Proposal:** Allow others (e.g., Institutional administrators or collaborators) to view, edit, or submit the proposal.
4. **PI:** Complete all required fields that include PI's name and contact information, and level of effort (%) that will be allocated to the proposed research project.
5. **PI Demographics:** Providing this information is optional.
6. **Institution and Contacts:** Provide the Institution name, address and type of organization and requested contact information of the signing official.
7. **Key Personnel:** List and provide contact information for key persons.
8. **Scientific Abstracts and Impact Statement:**
 - Provide a general audience abstract (non-technical) (2,000 characters including spaces max) and a technical abstract (3,000 characters including spaces max) that concisely describe the background, rationale, specific aims, experimental approach including model system and statistical approach, anticipated outcomes and impact of the project. Note these abstracts may become public if the award is selected for funding, therefore, it should not include any proprietary information.
 - Impact Statement: Statement of Proposal's Benefit to the field of radiation oncology (1,000 characters including spaces max).
9. **Other Support:** List any additional research support that the PI currently holds. Include Project Title, Funding Source, Project Status, Award Number, Start and End Dates, Person Months, and Overlap.

	<p>10. Research Assurances: Indicate status of IRB/IACUC approvals as applicable, use of recombinant DNA, biohazardous materials, genetically engineered organisms, or fetal tissue.</p> <p>11. Entry Documents: Upload the below required entry documents.</p> <ul style="list-style-type: none">• Research Plan (10-page limit): Project description to fit within the proposed project period and should include:<ul style="list-style-type: none">○ Background○ Preliminary data and figures (if applicable, but not required)○ Specific aims○ Experimental design/methods○ Statistical analysis plan○ Anticipated outcomes○ Potential pitfalls and alternatives○ Significance○ Future directionsReferences should be included but do not count towards the 10-page limit.• Biosketches (5-page limit): The applicant and key personnel must each submit a biosketch including a description of support for the proposed project, a list of relevant publications and currently funded research projects. Either DoD or NIH format will be accepted.• Budget and Budget Justification: Submit a detailed budget (can be prepared using the NIH budget form e.g. PHS 398) and Budget Justification with a breakdown and description of annual estimated costs. NIH Fiscal Year 2022 Salary Cap will be applied to any supported individuals in the proposed research. Funding cannot go towards supporting salaries of mentors or collaborators. Funding for technical support is acceptable. Costs for attending at least one ASTRO Annual Meeting (either virtually or live) to present the project's research findings can be included in the budget.• Letters of support: An Institutional letter of support is required to indicate the level of commitment from the Institution to this award, and the Institution's acknowledgement that the allowable indirect cost rate is up to 28%. Optional letters of support from collaborators can be appended but are not required. Institutional and/or collaborators' commitment(s) to supplement funding for distinctive components of an overall research proposal is allowable but not required. Any key personnel's support should be included in the biosketches, not the support letters. <p>12. Validate: Review entire proposal for missing required information.</p> <p>13. Signature Page: Before submitting the entry, complete all fields within the signature page. An electronic signature is required from the Applicant/PI, and a Signing Official from the applicant's institution.</p>
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	<p>Entries will not be considered for review if required signatures are missing.</p>
<p>MERIT REVIEW</p>	<p>All proposals will undergo a rigorous peer review by the ASTRO Challenge Judging Panel. Reviewers are members of the ASTRO Scientific Review Panel and ad hoc experts in the field. A study section consisting of researchers with expertise in the areas and topics of each grant will review the entry for scientific merit and appropriateness for funding.</p> <p>Based on the merit review ranking, the ASTRO Challenge Judging Panel will make its final recommendations of entries to receive the ISR grant funding as allocated by Pfizer and Myovant Sciences under this Challenge program.</p> <p>Review Criteria:</p> <p>Selected proposals will have strong scientific merit and impact, possess an innovative and transformative approach, and demonstrate potential for progression to the clinic.</p> <p><u>Overall Impact</u> Reviewers must provide an overall impact score taking into consideration the criteria below.</p> <p><u>Scored Review Criteria</u> Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An entry does not need to be strong in all categories to be judged likely to have major scientific impact.</p> <p>If the proposed research includes clinical study, the reviewers will consider that any clinical study may include study design, methods, and interventions that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical study relative to the available resources.</p> <p><i>PI</i></p> <ul style="list-style-type: none"> • Are the PI's prior training and research experience appropriate for the scope of this Challenge? • Is the PI's academic, clinical (if relevant), and research record of high quality? • Does the PI have the potential to organize, manage, and implement the proposed research? • Does the PI have training (or plans to receive training) in data management and statistics relevant to the proposed research? <p><i>Research Plan</i></p>

	<ul style="list-style-type: none">• If relevant, has the PI presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?• If human subjects research is proposed, has the PI proposed a targeted enrollment table that will balance the race, ethnicity, and sex distributions to resemble the demographics of the proposed human subjects cohort that is scientifically justified?• If human subjects research is proposed, has the PI included a specific and tangible recruitment plan to reach sufficient diversity and underserved populations as the targeted enrollment?• Are the proposed research questions, design, and methodology of significant scientific and technical merit?• Innovation: Does the entry challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new entry of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?• Is the prior research that serves as the key support for the proposed project rigorous?• Has the PI included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?• Has the PI presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?• If relevant, are the scientific rationale and need for a clinical, feasibility or ancillary study well supported by preliminary data (although not required), clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?• If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?• If relevant, is the clinical or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study necessary to establish feasibility of a future clinical trial?• Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?• Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?• Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered?
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	<ul style="list-style-type: none">• For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding? <p><i>Consultant(s), Collaborator(s)</i></p> <ul style="list-style-type: none">• Is there evidence of the consultant's and/or collaborator's previous experience to support the PI(s)?• Is there evidence of the consultant's and/or collaborator's current research productivity and peer-reviewed support?• Is active/pending support for the proposed research project appropriate and adequate? <p><i>Environment & Institutional Commitment to the PI</i></p> <ul style="list-style-type: none">• Is there clear commitment of the sponsoring institution to ensure that the required minimum of the PI's effort will be devoted directly to the research described in the entry, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?• Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the PI, adequate and appropriate?• Is the environment for scientific development of the PI of high quality?• Are the administrative, data-coordinating, enrollment, and laboratory/testing centers, appropriate for the study proposed?• Does the entry adequately address the capability and ability to conduct the proposed research at the proposed site(s) or centers? If applicable, are the plans to add or drop enrollment centers, as needed, appropriate? <p><u>Additional Review Criteria</u></p> <p>As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact score, but will not give separate scores for these items.</p> <p><i>Protections for Human Subjects</i></p> <ul style="list-style-type: none">• For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials.• For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: (1) the justification for the
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	<p>exemption, (2) human subjects involvement and characteristics, and (3) sources of materials. For additional information on review of the Human Subjects section, please refer to the NIH Guidelines for the Review of Human Subjects.</p> <p><i>Inclusion of Women, Minorities, and Individuals Across the Lifespan</i></p> <ul style="list-style-type: none"> • When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals across the lifespan (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the NIH Guidelines for the Review of Inclusion in Clinical Research. <p><i>Vertebrate Animals</i></p> <ul style="list-style-type: none"> • The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other entry proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the NIH Worksheet for Review of the Vertebrate Animal Section. <p><i>Biohazards</i></p> <ul style="list-style-type: none"> • Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed. <p><i>Authentication of Key Biological and/or Chemical Resources</i></p> <ul style="list-style-type: none"> • For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources. <p><i>Budget and Period of Support</i></p> <ul style="list-style-type: none"> • Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.
<p>PROGRAM CONTACT</p>	<ul style="list-style-type: none"> • Email questions about this PA to the Department of Scientific Affairs at science@astro.org.

	<ul style="list-style-type: none">• Technical questions about the Pfizer ISR Grant System should be directed to their customer support at GlobalMedicalGrants@pfizer.com.
GRANT AGREEMENT REQUIREMENTS	<ul style="list-style-type: none">• If your entry is recommended by the ASTRO Challenge Judging Panel, your institution will be required to enter into a written grant agreement with Pfizer and Myovant in order that support can be provided. Please click here to view the core terms of the agreement (though note that this is not the complete contract template). Neither Pfizer nor Myovant have the resources to negotiate grant agreements, so please ensure that your institution is able and willing to abide by these terms before proceeding with your application.